TECHNICAL PROGRAM

20th Annual National Conference on Managing Environmental Quality Systems
Quality Management Solutions for Today's Environmental Challenges

Keynote Address: **The Honorable Miriam Naveira de Rodón**
Justice of the Supreme Court of Puerto Rico

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  Clay Ogg U.S. EPA

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  Darby Chellis, Jessica Yocum, Marasco Newtown Group

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THE IMPORTANCE OF QUALITY ASSURANCE TO SCIENCE IN THE COURTROOM IN COMMON LAW AND CIVIL LAW SYSTEMS

Hon. Miriam Naveira de Rodón
Associate Justice
Supreme Court of Puerto Rico

Good morning. First of all I would like to thank Nancy Wentworth, Quality Staff Director of the Office of Environmental Information and George Brillis, Quality Assurance Manager for the Environmental Sciences Divisions, for affording me the opportunity of addressing such a distinguished group of quality management professionals.

As the world grows more complex, society globalizes and technology advances, the importance of quality management professionals, as essential components in the decision-making process, in both the public and private sectors, will become more evident. The delicate balance that must be struck between technological advances and economic interests on the one side and public health and environmental concerns on the other, will inevitably thrust you in the middle of this scientific fray, as either arbiters or principal players, positions you will have to be well prepared to uphold. This may require from you at least a smattering knowledge of the basic principles of some of the world's main judicial systems, for in most cases, it will be in the courts where balances will be made and hypothesis tested. Your expertise as quality management professionals and as experts in your various fields may be required outside the united states. The ever increasing presence of multinational corporations and united states' involvement as a world leader makes this unavoidable.

The purpose of this presentation is to share with you some of my views and concerns on the importance of quality assurance of science in the courtroom. This I will do from the point of view of a judge who has had the unique opportunity of knowing and working in two different judicial systems, common law and civil law. the focus will be mainly on the role of judges in the united states as gatekeepers of the admissibility of scientific evidence. I will, nevertheless, strive to intersperse some comments as to how some of these matters are dealt with in the civil law systems. I am talking about the systems which prevail in Mexico, Central and South America, most of the Caribbean and Europe, and of course, all of the former European colonies, with the exception of the United Kingdom. I will also endeavor to give you some general pointers as to how best convey your knowledge and expertise to the courts so that it will be properly utilized and achieve the desired effect. It is in the best interest of both, the scientific community and the judicial system, to jointly work towards assuring the quality of the science the expert witness brings into the courts. So, in a nutshell, my first all encompassing advice is ***know the judge, but above all know the system.*** Let me warn you, at times this may not be an easy task.

Science relies on quality assurance and quality control to attain high quality data and integrity in research studies. For scientists all over the world, quality assurance is invaluable since it inquires into whether or not the appropriate experimental checks were performed, and ensures that appropriate quality control is followed.[1] Quality control is the system of checks used to generate quality data from which reliable scientific opinions may be derived. Quality Assurance determines if the proper system of checks has been applied. The goal of these procedures is to collect data that is not only scientifically and technically sound, but also thoroughly documented and cost effective, as well as legally defensible.[2] Quality assessment and control procedures allow scientists to answer and judges to ask questions regarding the consistency and correctness of the sampling, processing and analysis techniques. It also answers questions dealing with lost, damaged or uncollected samples, as well as if the integrity of the data record has been maintained and documented, and if the data collected is comparable with similar data collected elsewhere and if the study results are reproducible. All these are pertinent criteria to scientific quality assurance.

It must be kept in mind that the issues of quality assurance and quality control are decided by scientists; but issues concerning the admissibility of scientific evidence in the courts are decided by judges. Judges are taught, through their legal training, the intellectual skills to analyze legal problems. Scientists are taught to analyze empirical questions and proposed answers. These differences at times place a judge in a weak position by not knowing precisely what questions need to be asked in order to test the empirical claims, or how to evaluate the opinion offered as an answer.[3] Scientific concepts are routinely applied in the courts by judges, lawyers and juries, usually all uneducated in the scientific area of expertise that is being brought to their consideration. The judge's task becomes increasingly difficult when the expert witness does not take into account the fact that every profession has a series of unarticulated premises and assumptions, known to other experts in the field, yet unknown to a layperson, in this case a judge. The knowledge of these premises and assumptions may be essential to the proper understanding of the expert witness' opinion. Although the structure of our legal system provides rules and procedures that help judges avoid tripping over these flaws in communication in an area foreign to them, they are imperfect, and will not always avoid critical mistakes and misjudgments.

The scientific and legal communities differ fundamentally in how they view their respective disciplines, which serve different purposes. Science is frequently directed towards a particular purpose and generally begins with "laws" that are purely descriptive. It may not seek to control or judge the phenomena of the physical world, just to explain it. The legal system, on the contrary, attempts to prescribe rules for human conduct according to certain standards, values and societal goals. The legal system is concerned with what "ought to be" while science is concerned with what "is". Science endeavors to identify immutable "facts" so as to apply them to the solution of problems.[4] The legal system does not set forth its "facts" as immutable. Legal facts and legal "truths" may be merely a reflection of how society wishes to order itself at a given time. They may or may not reflect reality, even though courts strive towards this goal.[5]

Usually, when judges make decisions outside the scientific sphere, they need not concern themselves with their scientific validity, since they are just following the dictates of society. But when the decision is within the scientific sphere, our social legal structure dictates that judges make scientifically correct decisions.[6] This brings to the forefront the legal system's need for scientifically valid inputs. Without valid data, the legal system cannot decide when and if social policy concerns should override or modify scientific "truths".

In the United States, courts are required to follow precedents. Under this system, when an appellate court decides a scientific evidence issue, specially one related to a novel technique, lower courts and other courts accept the result without seriously questioning the technique.[7] Judges in lower courts are expected to follow precedents, while scientists are expected to question findings and ask new questions.

At this point I would like to bring to your attention the fact that the methodology of precedent is not followed in the civil law system of cassation. Thus, under these systems, lower courts are not required to follow an appellate court's decision and appellate courts may issue inconsistent opinions in different cases. In civil law systems courts will make reference to prior cases only if they are convinced of the persuasive value of the reasoning utilized. The courts usually rely on studies and analysis by respected commentators, not prior cases. Case law is a foreign concept to these systems.

Sometimes, judges in the United States, because their rulings are based on legal precedents and not on scientific analysis, may give prior decisions undue weight. From the point of view of the scientific community, the advancement of knowledge depends on scientists' rigorous questioning of theoretical propositions until their validity is established. In contrast, in the legal system, lower courts, faced with the doctrine of precedent, may be hesitant to overrule or modify erroneous decisions from appellate courts, even if they are clearly wrong.[8] Few trial judges are willing to correct a higher court's mistake and, thus, until the appellate court deals with its own error and resolves it, the bad or erroneous precedent stands and will probably be followed.

With regards to the admissibility of scientific evidence, the trial judge begins by scrutinizing the expert witnesses' qualifications and the admissibility of evidence in general, before determining it is reliable and relevant and allowing it to be presented to the jury. The purpose of this screening is to prevent invalid, prejudicial, confusing or irrelevant evidence from getting to the trier of fact, the jury. This is done because, the jury, impressed by an expert witness' qualifications and the mystic that emanates from this knowledgeable discourse in areas foreign to the lay person, may give weight to unreliable and irrelevant evidence. This rationale mandates that juries only receive scientific evidence that is based on valid scientific principles and reliable data.

In our judicial process, the importance of pretrial inquiry regarding an expert witnesses' testimony, should not be underestimated. at this early stage of the proceedings, issues of admissibility are usually decided, in other words, what gets and what does not get to the jury. The court may also decide if it will appoint an independent expert or special masters, all crucial matters to both plaintiff and defendant. In our adversarial system, if the judge does not exercise proper control of pretrial inquiry it may degenerate and merely become a battle between lawyers and the experts before a nontechnically oriented, and at this point I would say disoriented, judge.[9]

You must bear in mind that lawyers have been considered a highly pretentious bunch who have the gall of judging the competency of members of other professions, professions of which they know nothing or very little. This has been called the snobbish hypocrisy of law. This brings to mind a book entitled "Woe unto you, lawyers!" written by Fred Rodell, a Yale law professor. I read this book when I was just starting law school and I must admit, it helped me put things in their proper perspective and subdued my emerging snobbish ego. As I remember, for I have not been able to find this book again, on one of the chapters Rodell comments a supreme court decision which dealt with a claim for damages for the improper construction of a bridge. Not being an engineer, he asked his friends at the engineering

department at Yale to analyze it. They unanimously concluded that had the bridge been constructed the way the court determined was correct, it would have fallen when the first car attempted to cross it. Obviously there was no quality assurance in the scientific evidence which was brought before the court in that case.
in civil law systems, where trials are non adversarial and you have no juries or ones quite different from what you are used to and where there are no oral evidentiary hearings, the power of the judge is much greater. He or they, depending on the system, have control of law and facts, and the rules of evidence, as you know them are inapplicable. The judge is not the gatekeeper, he rules the roost.

In our judicial system, quality assurance and quality control of science must provide the framework to assist judges in the evaluation of the issues of reliability and validity, which are fundamental in the determination of the admissibility of scientific evidence. The admissibility of scientific evidence in certain types of cases can be a highly complicated issue for the judge. For example, in environmental cases, issues associated with causation can be quite tricky. In toxic tort cases, as well as other types of tort litigation, a plaintiff must prove that the acts or omissions of the defendant were the proximate cause of the injury.

Proximate causation involves a policy determination made by the court that requires the plaintiff to demonstrate that a defendant's action occurred through a linear chain of events that were not broken by an intervening third party.[10] **Factual causation** is an objective determination on what is known about a course of events and is generally decided by a jury. It can be a stumbling block in proving proximate cause.

And to make matters just a little bit more complicated, the legal process also requires plaintiffs to prove general and specific causation. **General causation** refers to a finding that a particular substance was capable of causing plaintiffs injury and, **specific causation** requires that plaintiffs demonstrate that the substance actually caused the alleged injury.[11] In a toxic tort context, this entails that plaintiff show that he or she was exposed to an identified harmful substance; that the substance was capable of causing the type of injury for which plaintiff is seeking redress and that it did in fact cause the injury. Plaintiff must also prove that defendant was responsible for manufacturing or disposing of the toxic substance that resulted in the injury or disease.

Commentators in the united states recognize as one of the major difficulties for plaintiffs in toxic tort cases, that they often only have probabilistic rather than concrete proof of their injury. this makes it difficult to prove **specific causation**.[12] Plaintiffs can prove **general causation** by showing that exposure to a toxin is capable of producing their injury. Proof of specific causation may be more complex, the identification of the specific or exact chemical or chemicals that caused the plaintiff's injury can be extremely difficult. The literature on this subject provides us with some examples, such as: the creation of unidentifiable toxic substances due to the intermingling of different chemicals over a relatively long period of time. This situation can be found in toxic waste dumps. Even assuming in such circumstances that plaintiff is able to prove exposure to harmful chemicals, he or she will then be faced with the additional difficulty of identifying the exact substance to which he or she was exposed and that such substance in fact caused his or her injury or harm.[13]

Nowadays new toxic substances produced by companies may be insufficiently tested as to their potential adverse health effects. Many times, even with detailed studies or testing, science is unable to directly connect the substances with the illnesses. Often, the studies only hypothesize as to this cause-effect relationship.[14] Of utmost importance in the causation criteria is the consideration of the extremely long latency period between an exposure and the onset or manifestation of a disease. This latency period further complicates the finding of a causal link, which, as science tells us, can be affected by intervening factors such as genetics and lifestyle choices.[15]

Due to the difficulties associated to causation in environmental cases, plaintiffs rely on expert testimony and epidemiological and toxicological studies to prove that they are among the group of people who could have contacted the disease through exposure to the toxic substance in question. Epidemiological studies examine the relationship between a disease and the factors that cause it by comparing statistical incidence of the disease in a population exposed to a causative agent, to incidence of that disease in an unexposed population.[16] Epidemiological studies use data to show a correlation between a certain substance and a particular disease. Findings are tested and validated by exploring factors, aside from statistics. In general, according to the scientific experts, when epidemiological studies are combined with proper expert scientific testimony, these studies can help make valid inferences of population-wide causation.[17] Nevertheless, as can be readily ascertained from what I have just explained, in an individual case, these studies are usually insufficient to prove **specific causation.**

Plaintiffs in toxic tort cases, also rely on toxicological studies. These studies are more problematic in the courtroom than epidemiological studies.[18] The main problem associated with them is the difficulty of extrapolating the results of animal lab tests to humans. This is due to the differences of each species' reaction to toxic substances and the high dose level used in animal experimentation.

I sincerely hope that the dilemma faced by the courts concerning admissibility issues, specially in toxic torts cases, will be alleviated as science progresses and can offer the courts valid and reliable evidence. quality management professionals must strive towards this goal. After all, bad science in the courtroom makes for bad law and unjust decisions. Courts forced to make rulings about the admissibility of scientific evidence based on a small body of poorly designed studies, or no studies at all, are going to have a much harder time making good, fair, and just decisions. Courts nowadays are required to evaluate scientific evidence in much the same way as scientists evaluate science,[19] yet, we must keep in mind that the evaluators in the courts are still judges trained as lawyers, not scientists.

Citizens expect courts to be reasonable, fair and just in their decisions.[20] When court decisions are based on scientific evidence of bad quality, the court's decision is seen as unreasonable, mistaken and poorly construed. In the end, it constitutes bad law undermining the respect society owes both the judicial system and the scientific community. An alliance between science and law serves well the purpose of validating and advancing scientific knowledge while upholding justice. Both the scientific community and the judicial system must work hand in hand towards this goal. Although this sounds like an ideal situation where cooperation should be the order of the day, this is not always so.

In malpractice tort cases against some professionals, the plaintiff may find himself in the awkward and detrimental position of not being able to obtain a qualified expert to prove the allegations even though they may have a valid claim. Members of a given profession, the defendant's peers, are often reluctant to testify against a fellow colleague. This situation has given rise to quite a few very profitable corporate businesses, which guarantee, usually to the plaintiff, that they will find an expert in whatever field is needed and that this testimony will support the allegations set forth in the complaint. these situations are not always beneficial to the image of either the judicial system or the scientific community. By the way, you'd be surprised at the impressive qualifications some of these "made to order experts" have.

In the United States, the first attempt, in the federal judicial system, at regulating the use of scientific evidence occurred in 1923, when Judge Van Orsdel from the circuit court of appeals for the District of Columbia circuit, issued the first guidelines for the admission of expert scientific testimony.[21] He created the now infamous Frye Test, commonly referred to as the "general acceptance" test. Frye v. United States[22].

The Frye opinion, which dealt with a type of lie detector test, stated that, in determining whether expert testimony should be admitted, a court must consider its acceptance within a particular field of science. The test developed by the court required a judicial inquiry into whether the expert's testimony was based on generally acceptable scientific principles.[23] In spite of its wide acceptance in the decades following its creation, critics pointed to its inability to adapt to the rapid growth of scientific knowledge. A strong recognition of its inadequacies began to surface in the 70´s, causing some courts to develop other standards for the admissibility of expert scientific testimony.[24]

The next landmark case, Daubert v Merrell Dow Pharmaceuticals, Inc.[25], was decided after the enactment of the federal rules of evidence in 1975. The court determined that the common-law standard of "general acceptance" of the Frye Test had, in fact, been superseded by the enactment of the federal rules of evidence. It reiterated that Rule 402 is the "baseline" for determining the admissibility of evidence and that it applies to determine the relevancy of evidence. In the federal rules 'relevant evidence' is defined as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence".

Although the court established new guidelines to evaluate the admissibility of expert scientific testimony, the trial judge was still responsible for screening the evidence to "ensure" that what is admitted is "not only relevant but also reliable". He has to inquire into the relevancy-reliability value of the proffered expert scientific testimony. This relevancy-reliability analysis requires the determination of: (1) whether the testimony is based on scientific knowledge, and (2) whether the testimony assists the trier of fact in understanding or determining a fact in issue.

The term "scientific" according to the court, implies a grounding in the methods and procedures of science, while knowledge implies that it must not be based upon a "subjective belief" or "unsupported speculation" and that it "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds". It recognized that expert scientific testimony did not need to be based on certainties, because "arguably, there are no certainties in science". The court stated that "in order to qualify as scientific knowledge' an inference or assertion must be derived by a scientific method".[26]

Under Daubert, for a court to determine whether expert testimony is based on scientific knowledge, a four-prong inquiry must be carried out. The court must look into whether the proposed testimony has been (1) “tested”; (2) “subjected to peer review and publication”; (3) attributed to a “known or potential rate of error”, and (4) last but not least, it must determine whether it has achieved a sense of “general acceptance”. The court recognized that the testing of a hypothesis is the cornerstone of science.

Although the court acknowledged that publication could not serve as the “sine qua non of admissibility” because it did “not necessarily correlate with reliability”, it still insisted on a determination of this issue prior to admitting the proffered testimony. It recognized that an absolute requirement of peer review and publication would mandate that some special techniques or theories be ruled inadmissible because “some propositions... [would be] too particular, too new or of too limited interest to be published.” However, it determined that “submission to the scrutiny of the scientific community is a component of 'good science', in part because it increases the likelihood that substantive flaws in methodology will be detected”.

The court also recognized that “widespread acceptance [could] be an important factor in ruling a particular evidence admissible, and a known technique that has been able to attract only minimal support within the community, [could be] properly... viewed with skepticism.” But, “the focus... must be solely on principles and methodology, not on the conclusions that they generate”.[27]

Once the relevancy-reliability issue is resolved, the court must then determine whether the admission would create unfair prejudice to one of the litigants, or confuse or completely mislead the jury. it must be recognized that no matter how flexible the admission of expert testimony criteria is, inevitably, on occasions, the gatekeeping of the trial judge will prevent the jury from learning authentic insights and innovations.

At this point I would like to note that although most state judicial systems follow the pattern set forth in the federal rules of evidence, there may be some important variations between the different states. Their respective judicial systems may also vary from the federal model.

The next important case in this area, General Electric Co. v. Joiner[28], was decided in 1997. It held that abuse of discretion is the correct standard for an appellate court to apply in reviewing a district court’s evidentiary ruling, regardless of whether the ruling allowed or excluded the expert testimony. The court rejected the suggestion that a more stringent standard is permissible when the ruling, as in the joiner case, is “outcome determinative.”

As a general rule, if the ruling on the admissibility of evidence does not end the case by mandating its dismissal, it is considered an interlocutory determination, and in federal courts, not usually subject to immediate appellate review. The party affected by the ruling will have to wait until the case is finally resolved to be able to review what he or she considers an erroneous admissibility determination. In states where immediate appellate review of interlocutory determinations is permitted, the impact of this procedural rule may not be as great, since immediate review of an admissibility ruling would avoid long term uncertainty since the proceedings, will continue with what could be an erroneous ruling in the admission or exclusion of key expert testimony.

As I am sure you are all well aware, the Daubert decision has not been immune to scholarly criticism by the legal community. Critics state that it fails to provide guidance as to how to interpret and implement the "general observations" it sets forth. They also argue that there is no guidance on how to evaluate what is "adequate testing" thus promoting arbitrary evaluations leading to unpredictable and inconsistent results.[29]

Concerning peer review, they point to the fact that the acceptance of the offered testimony within a community of peers is a source of continuing controversy. There is no recognized superior authority that adopts an official position on behalf of the scientific community. This requires that the trial judge make an independent judgement as to the validity and reliability of individual peer journals. Omissions of relevant publications from this analysis may be unintentional though critical. The problem is that the jury may be denied relevant information or may be given prejudicial, unreliable information.[30] Critics also consider that the court's holding equated peer review with validity, although publication in scholarly journals does not assure the accuracy of the hypothesis. Peer review is said to have many limitations, just as the lack of publication in a peer-review journal does not indicate unreliability.[31]

The new test under Daubert has been strongly criticized because of its overly conservative view and unaccepting attitude towards novel scientific techniques.[32] [33] In 1999 the Supreme Court decided Kumho Tire Co. v. Carmichael[34] , holding that the trial court´s gatekeeping obligation extended to all expert testimony. The court explained that the factors identified in Daubert may or may not be pertinent in all cases in assessing reliability, depending on the nature of the issue, the expert´s particular field of expertise and the subject of his or her testimony. The court also pointed out that even for scientific evidence, not all the factors will always be relevant.

After Daubert, appellate courts are considering the issue of admissibility of scientific evidence as a question of law. Accordingly, they do not refrain from looking beyond the record, **doing their own research** or from deciding if the trial court was correct in its assessment of science.[35]

Now, by treating scientific evidence admissibility decisions as a question of law, appellate courts bring about a more consistent treatment of such evidence as well as an increase in the accuracy of decisions by increasing judicial scrutiny. Regarding rulings on the admissibility of scientific evidence as questions of law, makes them, as precedents, applicable beyond the case at bar. As questions of law, these rulings have nothing to do with the credibility of witnesses or anything else that a trial court is in a better position to assess than an appellate court.[36] The issue of admissibility of scientific evidence stands or falls on the body of scientific knowledge brought before the court. The appellate courts are considered to be in the same, if not better, position to evaluate scientific literature, than the trial court.

We must always keep in mind that science is as good as the scientists who perform the studies and procedures. quality assurance professionals have to monitor their studies and processes, so as to make sure science lives up to its responsibilities of setting its own standards. Courts rely on the scientific community concerning these elements. Scientists are the gatekeepers of the quality and reliability of scientific knowledge while judges are the gatekeepers of the admissibility of scientific evidence in court.

The Daubert Test has been considered as an increased emphasis on the truth-finding value of trials.[37] The decisions made by the courts on admissibility of scientific evidence represent an opportunity for the courts to win or retain public confidence. Daubert is considered to have placed a high value on truth-seeking. Although this, at times, may momentarily produce a loss of public confidence, since scientific truth and what the public has faith in, may not always be the same. Nevertheless, the filtering out by judges of any and all empirical claims that cannot be demonstrated to be valid, in the long run will enhance public trust and confidence in the judicial system and the scientific community.[38]

Some commentators assert that admissibility rules influence the nature or direction of the development of science, since court decisions can serve as an incentive to do more and better research or as a disincentive for doing so.[39] If judges are evaluating scientific evidence more like scientists evaluate it, scientists can assume judges will be interested in the quality assurance and quality control procedures that enhance the validity and reliability of the research methods and techniques used. Undoubtedly, under this vision, quality assurance professionals have a heighten role in the procurement of good science.

When court decisions exclude scientific evidence that cannot establish causation or where there are no epidemiological studies linking exposure to a toxic substance with disease, these decisions may validly constitute an incentive for researchers in the area to perform further studies on the subject. Although courts certainly are not setting the agenda for future research, they may influence this agenda. Probably, one of the most important contribution of law to science consists in bringing to the forefront the importance to the judicial process of the quality assurance standards that science must set for itself. This constitutes an important incentive to quality assurance professionals to maintain high levels of performance in their particular fields. the influence of law on science is certainly an area that needs further study and research.

Current trends suggest that courts will inevitably become more liberal in their considerations of novel scientific techniques. The advance and development of science in the past century justifies this tendency. It is difficult to imagine a court without rules but when dealing with science, the rules have to take into account the way science is developed. Scientists must become aware of the judicial process, its goals and purposes, and the differences between the real world and the facts that are determined in court. There is no reason why science and law cannot be partners in the search for truth and in fulfilling the goals of the judicial system. **I am confident that we can count on you.**

Thank you.
Muchas Gracias.

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IMPROVING THE QUALITY OF DATA USED IN ENVIRONMENTAL ECONOMICS RESEARCH

Clayton Ogg
U.S. Environmental Protection Agency

Abstract - Valuing environmental goods through contingent valuation and through other survey techniques is difficult because of the lack of traditional markets for those goods. EPA provides leadership in overcoming these challenges, using focus groups, workshops, handbooks, and teams of distinguished economists to obtain more reliable economic data from the surveys.

Agency economists have provided leadership also in employing production economics tools to identify win-win approaches to solve pervasive and neglected environmental problems.

In addition, we exploit the speed of sophisticated computers, building field run-off models into economic models and aggregating results from tens of thousands of field sites. These very flexible models provide much more credible, site specific analyses than previous models, and they offer flexible and efficient remedies to support Total Maximum Daily Loads and other new programs.

Past environmental programs committed hundreds of billions of U.S. dollars to achieve environmental benefits. Policy makers are keenly interested in quantifying the economic benefits from these past investments, as well as any future investments in improving the environment. Although quantifying economic benefits from environmental decisions rarely, if ever, leads to confrontation or litigation, assuring the quality of economic data and analyses is critically important. EPA's economic analyses support important policy and programmatic decisions.

Of the many areas of research conducted by the Office of Policy, Economics, and Innovation, this paper will focus on three areas where generation of quality economic data appears most relevant to Agency decision making. 1) Agency economists collect primary economic data through their own contingent valuation (CV) surveys or use data from earlier CV surveys; these surveys face the immense challenges in developing reliable data, but provide a *direct valuation* of environmental products not sold in any market place. 2) Other studies employ agricultural production economics to quantify *producer benefits* from adopting nutrient planning and other technologies which benefit producers' bottom line--and the environment--by reducing the use of costly chemical inputs. 3) Economists also team up with physical scientists (such as those attending this conference) to build environmental indicators into economic models; these models are then used to identify *site specific benefits* as environmental decisions devolve to the local level through Total Maximum Daily Loads (TMDL) and other locally run programs. Agency economists continue to play a leadership role within their professions as they improve the quality of data and models in each of the above research areas and assure that the models, assumptions, and findings are employed correctly.

Each of these three areas of economic/environmental research offers unique contributions to support environmental decision making, and each offers it own set of challenges to those providing reliable data and models. These Quality Assurance (QA) challenges faced by economists are very different from the challenges faced by others attending this conference. After describing past efforts to assure the quality of data, the paper will suggest some additional measures that can be undertaken in the future.

Direct Valuation

Economists traditionally rely on the price of a good to represent its value to society. However, with environmental goods and services (such as national parks or clean air) there is no market in which a price, or value, of the good is revealed. Therefore, economists have developed alternative methods for estimating such values. Three of the most common such techniques are contingent valuation, hedonics, and travel cost methods. This paper will focus on the first technique, contingent valuation. Contingent valuation (CV) is a survey method that provides a hypothetical "market" in which individuals are asked to express a value for a particular environmental good or service. For example, a survey might ask individuals to express a willingness to pay to improve water quality in a particular lake from a boatable to a swimmable standard. These stated values can then be used as an input into benefit-cost analysis or policy decisions. CV is arguably the most widely used valuation technique at EPA because of its ability to capture non-use values (e.g., individuals who do not directly "use," or visit, a particular lake may still have a value for its water quality improvements) and its ability to be applied to many different scenario types. However, CV is also one of the most controversial methods because of the hypothetical nature of the survey methods. Designing these CV questions offers perhaps the greatest challenge in attaining reliable data and estimates (USEPA,2000).

Activities lead by National Center for Environmental Economics (NCEE) economists during the past year are illustrative of the Agency's efforts to improve the data from CV surveys:

- NCEE co-sponsored a workshop focused primarily on improving survey data obtained for CV studies, entitled "Stated Preference: What Do We Know? Where Do We Go?" (The term "stated preference" and "CV" are often used interchangeably). The workshop included sessions on theory and design, validity, and applications related to health and ecosystems. Some of the discussion focused on actual surveys supported by EPA, including a survey designed to value visibility improvements and one designed to determine the value older people place on health risks. Panel discussions addressed how agencies use these survey techniques, suggested research priorities, and identified ways to improve the survey instruments. Presentations and discussions from these and other workshops are published on-line (www.epa.gov/economics).

- NCEE is writing a Stated Preference Handbook for use by EPA economists and policy analysts. The Handbook will focus on evaluating the validity and reliability of existing CV studies, as well as how these issues impact the design of an original study. Topics will include the design of studies, survey administration, data analysis, and benefits transfer techniques. The Handbook will encourage analysts to incorporate methods of evaluating their survey instrument and results into their study design and to demonstrate why they adopted certain procedures. This document was reviewed internally and by distinguished reviewers from academia.

- Finally, several CV surveys conducted by NCEE during 2000, including surveys relating to benefits from improving drinking water, freshwater, and estuarine water, employed the quality assurance techniques favored by the above handbooks and a recently published "Guidelines for Preparing Economic Analyses." These techniques included extensive use of focus groups to test people's perceptions regarding the questions in the survey, as well as a review of the survey instruments by teams of distinguished economists.

Over the past two decades, EPA economists have relied on the above approaches to improve the data used by contingent valuation studies, hosting conferences which identify problems and solutions, developing handbooks and other publications outlining the latest techniques for improving the quality of data generated by contingent valuation and other surveys (Cummings, et. al.; Murdoch, et. al.; Sylvan Environmental Consultants; Martin Marietta Corporation), and supporting research by teams of the most talented economists. These studies identify problems with earlier studies and attempt to design and use new survey and focus group techniques which will improve the methodology as well as improve the actual estimates of environmental benefits (Anderson and Kobrin).

One study in 1990 attempted to overcome difficulties afflicting previous CV studies of air quality by confronting the diverse perceptions by survey respondents. Some survey respondents might see the Denver Brown Cloud as just that while others also perceive inhalation of harmful chemicals associated with the cloud (Schulze, et. al.). This study was typical of a number of CV studies funded by EPA over the last two decades in its use a large team of economists, and in some cases, psychologists, who work to identify problems in previous CV studies and attempt to overcome those problems (Anderson and Kobrin).

CV and many related benefit valuation techniques caught the imagination of resource economists. The work identified above attracts the attention of dozens of talented researchers inside EPA as well as many other resource economists across the U.S. Thus, the data problems associated with CV and related analyses are being addressed in a major way by many skillful economists, with excellent support from their profession. Some QA concerns in other areas of research, including those described below, do not enjoy the same high level of support, but EPA has provided much leadership in these other areas, as well.

Production Economics

Over two decades ago, agronomists identified large *potential* environmental gains in the form of reduced nitrogen fertilizer use (25-50 percent reductions) by delaying fertilizer applications until late in the Spring when plants were ready to use it (Bouldin, Reid, and Lathwell; Olson, et. al.) and by taking credit for farm produced nutrients already in the soil when applying fertilizer (Magdoff, Ross, and Amadon; El-Hout and Blackmere; Fox and Piekielek; Meisinger). Economists at EPA and elsewhere anticipated the questions policy makers might raise regarding these remarkable discoveries, such as, "Why are farmers not already using these nutrient planning technologies if they are so profitable, and what is the actual fertilizer savings achieved by farmers who have adopted these technologies?" Because policy makers invest as much or more in programs which support farm income as they invest in programs which improve the nation's environment, learning about producer benefits and environmental benefits from nutrient planning appeared to be a policy relevant area for economic research.

In contrast to the CV studies mentioned above, the production economics question appeared relatively easy. We could issue a call for research proposals which would focus on learning from farmers' *actual experience* in adopting and profiting from nutrient crediting technologies. This would be done in certain states which were ahead of the rest of the country in calibrating the nitrogen crediting technologies and making them available to farmers. Farmers know what you are saying when you ask 1) what they have spent on fertilizer and 2) whether they have used the late Spring soil test. Providing credible estimates in more than one state was considered desirable because policy makers, as well as economists, are naturally skeptical of win-win types of claims linking environmental improvements with producer benefits.

Economists in Pennsylvania, Iowa, and Nebraska, three states that were farthest along in adopting the improved nutrient planning technologies, conducted regional or state-wide economic analyses regarding use of these technologies. The Pennsylvania study (Hertle, et. al.) was the only one of the three which was supported by EPA. It found that within five years of its introduction, over a third of farmers in the state were already using the late spring soil test and that nitrogen fertilizer savings ranged from 25 to 40 percent. The Nebraska switching regression study (Fuglie and Bosch) was also based on a large survey of farmers and found a similar reduction in fertilizer applications and a 50 percent adoption rate for the deep soil test available in that state. The Iowa study (Babcock and Blackmere) used that state's extensive experimental data in a production function and again suggested fertilizer savings in the 25-40 percent range from Iowa' version of the late Spring soil test.

Publication in credible, peer reviewed journals supported the reliability of the these and other (Fleming and Babcock; Ogg,1999; Tractenberg and Ogg) studies which document producer benefits from improved management of fertilizer and livestock nutrients. Partly in response to these economic and environmental opportunities, policy makers have focused in the past four years on addressing the over abundance of nutrients on the landscape. This policy change occurred after decades of investing in costly remedies, such as tertiary treatment systems for urban nitrate sources. Past policies neglected the agricultural pollutants that provide by far the greatest share of nutrient loadings in U.S. streams (USEPA, 1990; Pucket). Nutrient planning, which typically includes soil testing or other methods of crediting farm produced nutrients, is the focus of "management measures" for coastal waterways (Ogg,1999), of hypoxia initiatives (Doering, et. al.), and of USDA' new Environmental Quality Incentives Program (Ogg,1999). Nutrient planning also will likely play a large role as States carry out new programs for confined animal feeding operations and develop Total Maximum Daily Loads (TMDL).

Production economics research, including the studies identified above, is very versatile and draws from a solid base of economic theory. Providing analyses that take advantage of this versatility lends credibility to the quality of the findings, as studies use very different data and approaches, yet arrive at mutually supporting conclusions. Since these production economics studies are much easier to carry out and since they produce reliable conclusions, much can be accomplished with relatively modest research investments.

Although not much of this production economics work is supported by the agency at the present time, economists looking at integrated pest management (IPM) have begun to find win-win sorts of opportunities that parallel those from the above nutrient studies. However, because of the large variety of

IPM techniques in use, documenting which IPM practices are beneficial to farmers and to the environment will be more challenging (Norton and Mullen).

Site Specific Research

Devolution of environmental decision making to the local level is another policy option aimed at reducing costs. TMDL programs and new USDA programs created by the 1996 Farm Bill attempt to offer flexible solutions that achieve environmental benefits in ways that are much more efficient than the past, one-size-fits-all approaches. These programs encourage States to rank local watersheds for treatment based on which watershed program offers environmental benefits at the lowest cost. For the watersheds targeted for early treatment, environmental goals are identified, and practices that most efficiently achieve those goals receive funding first.

In order to support the above ranking of potential watershed programs and to take advantage of the opportunity to achieve economic efficiency, economists work together with scientists from other disciplines to develop models with the capability to identify site specific benefits and costs. Working together, they combine economic models with the field run-off models and the stream models developed by physical scientists. Lack of the technical capability to model site specific impacts at a reasonable cost has hampered past efforts (Boyd) to advance TMDL programs, but researchers cooperating with EPA are producing models that provide the credibility and flexibility that is needed.

Early efforts to combine natural resource indicators into economic models involved building the Universal Soil Loss Equation (USLE) into linear programming models to analyze costs and benefits of soil conservation policy options. These models identified site specific land use changes from implementing various policies to reduce soil erosion. They were most useful in anticipating the erosion reductions and costs of policies such as the Conservation Reserve Program and Conservation Compliance (Ogg, Webb, and Huang).

However, as economists attempted to include phosphorus pollution as indicators in these linear programming models (Ogg, Pionke, and Heimlich), they had to address run-off. Run-off was a much more difficult problem than soil erosion because it had to be addressed for individual storms. Since computer models could not model large numbers of storm events at a manageable cost, modelers faced the impossible task of determining which storms could be considered as most representative or relevant. Also, the early linear programming models tended to average certain landscape characteristics over a geographic area rather than run the model for individual sites and then average the model's outputs for those sites. Depending on their disposition, physical scientists responded with wit, humor, or anger at how economists were using their models. The larger the landscape being modeled, the greater the opportunity to cause offense.

As computer capabilities have improved, EPA supported research which addresses the above problems. One recent cooperative study (Wu and Babcock) at Iowa State University ran the EPIC crop growth model every day for thirty years for ten percent of the 128,591 National Resource Inventory sample points within its12 state Midwestern region being modeled. It then used "meta-model" regression techniques to expand the results to the rest of the 128,591 sample points. Models used in this study had been calibrated and tested. The models are extremely flexible in outputting results to counties (as in the article sited above) or to impaired watersheds within the 12 state region. This is done by averaging the models' results for the sample points within the respective county or watershed. Sediment runoff at the field level, nutrient leaching and run-off at the field level, herbicide leaching and run-off at the field level, and soil carbon are the environmental indicators available within this model. In the Wu and Babcock analysis, nitrogen leaching and run-off was reduced by 15 to 30 percent in most counties using the win-win types of fertilizer management technologies (Fuglie and Bosch; Babcock and Blackmere; Hertle, et. al.) discussed above.

The Iowa model appears relevant to programs which require ranking watersheds to prioritize those watersheds which produce the largest benefits per dollar. They also could help in analyzing remedies to reach environmental goals set within the watersheds. If the model can be used in ways that avoid the costs of building a separate model for each TMDL watershed, considerable cost savings can be realized, although this author is not certain whether TMDL goals can be established without building a separate model for each stream.

Potential Problems Confronting Site-Specific Analyses

While the above Iowa model outputs physical science and economic information in a credible manner, many regional models used by economists (e.g. Doering, et. al.; Faith) still resemble more closely the older models described above. They lack the credibility which could be provided by modern, fast computers.

Serious problems have occurred, also, where models are used to address problems that they were not designed to address. One recent study (Faith, 1995) estimated the costs of managing nitrogen fertilizer by assuming that policy makers would reduce nitrogen to levels that starve the plant for nitrogen and reduce yields. This approach was suggested by the options that were available within the model, not by a review of the options under consideration by policy makers or by agronomists who assist farmers. In fact, agronomists insist that the technologies such as timing nitrate applications and taking credit for farm produced nutrients will not reduce yields, and these scientists work to ensure that yield reductions do not ever occur (Fox and Piekielek; Magdof; Meisinger). Policy makers focus on nutrient planning technologies which assure adequate nutrients to reach yield goals, but discourage nutrient applications beyond recommended amounts (Ogg, 1999). The Faith (1995) study failed to consider the technologies that farmers actually rely on to address the over abundance of nutrients on their land, as have other studies, before it (Ogg, 1978; Taylor and Frohberg).

Models are used in many ways. It is not the models, themselves, that pose problems, but rather how models are used. The same model that produced misleading estimates regarding the costs of fertilizer management provided an important contribution in a later study that considered the costs of energy taxes for agricultural producers (Faith, 2000). Because this model correctly portrayed producers' flexibility to shift to reduced tillage and other technologies in the face of higher energy costs, it was able to contribute important economic information to the policy debate regarding energy taxes and agriculture. For example, the analysis indicated that farm incomes would be affected only modestly and multiple resource conservation benefits would be realized.

QA for Economics Research

Economic research is very different from physical science research, in part, because we do not have a physical phenomenum, such as certain chemicals in a stream or in the air, that are there for us to measure. There are as many different economic phenomenum to measure as there are ways to measure them, and who is to say which theoretical model captures the more correct answer, or which offers the best measurement technique? Thus, the challenges to producing high quality economic data and analyses are very different from the challenges to producing physical science data and analyses.

Economic models used for quantifying environmental benefits are also not subject to the legal challenges associated with setting environmental standards. However, our studies need to be reliable and believable for use in important policy decisions. We are addressing this challenge in each of the research areas identified above.

EPA has provided leadership in addressing the major problems faced by contingent valuation and related studies as they attempt to value environmental goods which are not sold in the market place. The agency produces handbooks, works with focus groups, and assembles teams of the most knowledgeable economists to assure the quality of data. Many of the past studies attempted to remedy problems raised by earlier studies as teams of economists designed survey instruments that address the problems. These efforts will continue to play an important role in the coming year and beyond.

The challenges facing production function analyses are much less formidable. By working with economists who publish in credible, peer reviewed journals, and by employing a variety of research techniques, we can produce analyses that scientists and policy makers use.

The Agency also has supported development of site specific modeling tools that avoid criticism with regard to their physical science components. High speed computers allow researchers to assemble data at thousands of sample points and run a calibrated model for each sample point in a credible manner. Results for each point are then aggregated to the watersheds of interest. We need to employ these new, more reliable modeling techniques where they are most needed.

In the future, economists in OPEI will improve on the above measures by explicitly including data quality in the reviews conducted for grants and for contracts. Unlike the studies conducted by program offices, policy analyses have very wide flexibility as to which projects are funded. If research proposals do not assure appropriate use of data and models, an excellent remedy is to employ Agency resources elsewhere.

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ENSURING DATA QUALITY THROUGH EFFECTIVE LIFE CYCLE MANAGEMENT

Darby Chellis, Marasco Newton Group, Ltd.
Jessica Yocum, Marasco Newton Group, Ltd.

Abstract — By ensuring data is of the highest quality, the Environmental Protection Agency (EPA) is able to make informed decisions regarding budgetary needs, staff allocation, EPA-wide and program-specific goals, report program accomplishments, and plan appropriately for future activities. Quality data is imperative to accurately reflect program progress, justify and negotiate expenditures, and provide a unified EPA vision to internal and external parties.

Like every large organization in a data-reliant society, EPA faces many challenges in ensuring data quality. To protect the data integrity of an information system, a multi-dimensional team must be implemented and effectively managed, to support all aspects of a system's life cycle. This team must include a strong project manager, and requirements, development, independent third-party test, training, change management and user support staff. Each of these team members contributes to the quality of the system and ultimately the data tracked in the system.

The life-team must use their programmatic knowledge and technical expertise to create a system that not only supports data tracking and reporting, but facilitates data entry and thus data quality. The life-cycle team ensures that the needs of the users are clearly documented along with the detailed system specifications in order to promote knowledge sharing. Without such an integrated approach, an information system cannot adequately support the user community, nor can it provide the support mechanism where the information system can grow and change as programmatic policy changes. A dynamic life-cycle team thus ensures a dynamic and reliable information system.

By ensuring data is of the highest quality, the Environmental Protection Agency (EPA) is able to make informed decisions regarding budgetary needs, staff allocation, EPA-wide and program-specific goals, report program accomplishments, and plan appropriately for future activities. Quality data is imperative to accurately reflect program progress, justify and negotiate expenditures, and provide a unified EPA vision to internal and external parties. For example, data tracked in EPA's information systems is used to respond to Congressional and Freedom of Information Act (FOIA) inquiries. It is integral that this data be of the highest quality so that it accurately reflects ongoing trends and accomplishments. Quality data is also relied upon during internal EPA negotiations processes and externally with Congress to demonstrate where resources should be allocated for the upcoming fiscal year. Both planning and accomplishment data can be used to demonstrate a need for additional funding and to determine upcoming goals and objectives.

Like every large organization in a data-reliant society, EPA faces many challenges in ensuring data quality. To protect the data integrity of an information system, a multi-dimensional team must be implemented and effectively managed, to support all aspects of a system's life cycle. This team must include a strong project manager, and requirements, development, independent third-party test, training, change management and user support staff. Each of these team members contributes to the quality of the system and ultimately the data tracked in the system. For example, when documenting requirements, system analysts work to ensure that program processes are supported and that these requirements are translated into data entry screens that clearly display which data is required. Systems analysts also work to ensure that the system is thoroughly documented so that detailed knowledge of functionality and programmatic processes is retained. Test works with requirements not only to ensure a defect-free system, but also to ensure requirements are clear, concise and unambiguous for the developer. Developers work with the life-cycle team to build the system and provide technical input as to efficient database and application design implementation. Trainers work with system users, and the life-cycle team to ensure that users understand how to navigate the screens. Trainers also provide real life data entry scenarios and gather feedback as to the system's effectiveness in supporting day to day activities. User support staff, draw on the team's knowledge to ensure that when questions regarding functionality arise, they can quickly respond to ensure that data is entered and extracted in a timely manner. Change Management provides a vehicle for organized communication of data needs and works to prioritize these needs for system releases. Based on feedback from the user community and the life-cycle team, Change Management can assess trends, user needs and prioritize changes for future releases.

An information system is only as useful as the data put into it. The life-cycle team is integral to ensure continuity of design and knowledge sharing that protects data integrity.   The team must use their programmatic knowledge and technical expertise to create a system that not only supports data tracking and reporting, but facilitates data entry and thus data quality. The life-cycle team ensures that the needs of the users are clearly documented along with the detailed system specifications in order to promote knowledge sharing. Without such an integrated approach, an information system cannot adequately support the user community, nor can it provide the support mechanism where the information system can grow and change as programmatic policy changes. A dynamic life-cycle team thus ensures a dynamic and reliable information system.

Project Management

Every successful IT project owes its success to a strong, multi-disciplinary team. The first step that must be taken when building that team is to appoint a strong, experienced project manager. The project manager must perform many tasks throughout the life-cycle including: working with the customer to define the scope and goals of the project; communicating the scope, goals, and progress to the project team; allocating the correct staff and technical resources to the specific life-cycle phases; ensuring the team meets deadlines and milestones; establishing a plan if tasks must slip, motivating and mentoring the team throughout the life-cycle process to ensure that the team remains focused and performing at their optimum level; and ensuring the project stays within its financial and time constraints.

At the beginning of every IT project, the project manager must work with the client to define the scope of the project. The scope will define overall project timeframes, due dates, the responsibilities of each team member involved with the project, and expected costs. In addition, the scope will provide team members with a detailed document that can be referred to throughout the project life-cycle to provide a clear definition of client expectations, and deliverables. In addition, the project manager will ensure that the team understands the performance measures that will be used to be used to determine success. Finally, the scope may also include specific decision points in the project where requirements may change and decision makers will need to meet to arrive at a consensus.

The project manager will also work with the client throughout the project to establish and implement a clear project management approach. This approach will be based on the needs of the client and the strengths and weaknesses of the team. This approach will allow team members to understand expectations, as well as how to communicate progress, identify potential issues, and prevent risks. Understanding the expectations of the client and identifying the potential risks of the project up front will allow the team to plan ahead to eliminate obstacles before they arise.

The project manager will also work in conjunction with the lifecycle team and the client to develop a release schedule. This release schedule will include milestones where requirements will be gathered, reviewed and finalized; development will take place; where versions of the application will be released for testing and defects will be addressed. The schedule will also include a check point for client review and approval of the system and a proposed system release date.

A strong project manager, a clearly defined scope, and an effective management approach will ensure project success by ensuring that all team members understand the project goals and are working for the same expected end point.

Requirements

Requirements define the needs of the user and what functionality will be needed in the system to accommodate those needs. The role of the requirements analyst is integral to effective system development and maintenance as the system requirements drive all other phases of application design. As such, the success of an information system and the quality of the system's data is contingent upon the effectiveness of the requirements phase. To ensure success, the requirements analyst must be familiar with the scope and intent of the system that is being developed. The reason for building an information system is to track and retrieve data for specific purposes. The requirements analyst must have a firm understanding of the data needs and the ways in which the data are used. To fully understand these needs, the requirements analyst must know the workflow processes and programmatic needs and challenges facing the user community.

In order to gain this knowledge, the requirements analyst is responsible for leading application development/requirements sessions or interviewing and working with the various business units and the user community to understand the business function. Individuals designated to give requirements will include a representative sample of the user community, the system owner and other interested stakeholders. During requirements gathering sessions, the requirements analyst must be an effective facilitator. Participants need to clearly understand the purpose and scope of the system so that they can focus on the specific functional requirements that are integral to accomplishing the system's purpose. The process by which requirements will be collected, reviewed, and approved must also be established and clearly communicated. For example, a designated group of individuals with the final authority to make decisions when there is disagreement must be identified. Milestones or decision points must be established where this group will review and approve of the requirements.

As requirements are collected and analyzed, the requirements analyst must provide documentation of these requirements that is clear, concise and testable. To ensure that these requirements are of the highest caliber, a thorough quality assurance process must be in place. Both the test and development teams must review the documentation to ensure that the requirement is unambiguous, comprehensive, and can be met by the technology. This team review is designed to ensure that inconsistencies and omissions in the requirements can be addressed before development begins. In doing this, costly and complicated redevelopment will be avoided. Once the internal team review is complete, the requirements must be reviewed and approved by the individuals who gave requirements input and designated decision makers.

Establishing the requirements collection and review processes will protect data quality by ensuring that the necessary data is collected and can be reported in a meaningful way. Users will understand the intent and scope of the system and can focus their requirements by pinpointing key data and functionality needed to meet the information needs for which the system is being built. Reviewing workflow processes and procedures will help not only the requirements analyst and lifecycle team to understand the purpose of the system, but it will also help the user community and stakeholders to define and examine their business processes. Both the user community and the lifecycle team will have a unified understanding of the scope, purpose and direction of the system. An organized and well communicated approach leads directly to a purposeful system design.

Development

The development team provides the technical expertise required to build the information system. As such, the developer must review the requirements both for content and level of effort to implement to ensure that they are complete, concise and feasible. The developer should prepare a level of effort estimate so that the system owner will be aware of the complexity of the requirements. Upon reviewing these requirements, the developer's responsibility is to alert the requirements analyst of any additional questions or clarification needed from the user that must be addressed before the requirements can be implemented. They must also identify any software limitations that should be communicated to the appropriate stakeholders. Once requirements are reviewed and approved, the developer will document the technical approach that will be taken to see the requirements into fruition.

An organized approach for development will protect data quality by ensuring that a system is produced according to clearly defined requirements. Key data will be tracked according to the requirements and in the formats defined. Establishing check points throughout the development process will allow defects that could lead to poor data, data omissions or defects in various modules to be identified.

Testing

The role of the test team is to ensure that a defect-free system is developed according to requirements. To do this, the test team must review the requirements to ensure that they are clear, concise and testable. Based on the requirements, test must write test case scenarios that document the state of the system before the test is executed, the process for performing the test (e.g., steps involved in data entry etc.) and the expected results of the test. In documenting these test cases, the test team should include testing scenarios on real life data entry processes that would be followed by the user community. In this way, the test team will ensure that they identify any defects that would be encountered by the user community during normal operations. Test case scenarios must be reviewed by the requirements analyst to ensure that they are comprehensive and fully cover all intricacies of the requirement.

Test cases must be run on each function of the system and the results clearly documented. When the outcome of a test case does not match the expected outcome, the tester is responsible for entering defects and communicating their findings to the developer. When a defect is entered, it should include the steps taken to reproduce the defect and detailed information about the nature of the error. The test team will track and monitor the progress of the defects through to their resolution. To do this, testers may need to obtain feedback from the requirements analyst to clarify the requirements.
Test will work with the requirements analyst to certify that all requirements have been correctly implemented and the system is ready for deployment. The test team's job in certifying that a system is ready for deployment is to ensure that the system design exactly reflects the requirements and that these requirements have been interpreted correctly by the developer.

A systematic test approach will promote data quality by ensuring that defects that may lead to inaccurate data are identified and addressed before the system is placed in production. Testers also provide an additional check to ensure that requirements are implemented exactly as written and no interpretations or assumptions are made that are outside the scope of the requirement. Thus, through testing, the system owner and user community is presented with a functional system that is designed according to requirements.

Training

The role of the Training team is to provide a wide array of system expertise to all members of the user community. The training team is expected to provide all users with a complete understanding of the intent of the system, demonstrate how the system can be used in "real-life" situations, communicate how the system can be used, and demonstrate how to use the information and data that is entered. Trainers are expected to be fully knowledgeable about the application, supporting materials, and all training processes in order to provide appropriate and comprehensive training to all users. To do this, the training team must work closely with all other teams throughout the life-cycle process to ensure that they understand the scope of the system, the requirements and business needs driving the development of the system. Trainers must also understand how requirements were implemented (e.g., how the system was developed technically), and how requirements were verified through test.

The training team will begin preparing for training long before a system is implemented. The training team will do this because they will need to complete several steps before they can perform training. First, the training team must identify the user community, or who will be using the system once it is implemented. The training team must also identify the training or documentation needs of that community. In other words, the training team must identify how the users will be trained (in individual sessions, in group sessions, via video-conferencing, etc.) and what documentation they need in order to support their day to day activities (i.e., Quick Reference Guides, on-line help, etc.) The training team will then develop the course curriculum and materials for that user community and their needs including training scripts, training outlines, activity sheets, and documentation materials. At this point, the training team will work closely with the project team to perform practice training sessions to ensure that all system information is being accurately communicated to the user. The training team will work closely with the requirements team to ensure that the trainers have a complete understanding of the business needs driving the system and that they understand why the system was built the way it was. The training team will work closely with the development team to ensure that the trainers have a complete understanding of how requirements were implemented. Finally, the training team will work closely with the testing team in order to confirm that all documentation is accurate and thorough.

A complete approach to training will ensure that users are provided with the resources and the knowledge they need in order to accurately enter data into the system and/or get data from the system. In addition, a complete approach to training will ensure that users understand what data is being asked for and why. Understanding the information needs that lead to the creation of a system or new functionality can lend legitimacy to the information system. Without a strong training approach and documentation, the users will not be presented with the knowledge, or guidance they need to gain a complete understanding of the goals of the system and how their roles affect overall data quality.

Change Management

As organizations and their systems grow and the business needs driving requirements become more complex, the need for a clear, concise, well-defined way to manage change is becoming more and more important. Managing change is absolutely integral to assure high system and data quality and to make the best use of team resources. It is very easy for the number of enhancement requests, defect reports, and requirements issues to overwhelm a team that is not properly managed. This is why it is important to have a change manager in place who can effectively facilitate the change process. The change manager must ensure that changes are organized, reviewed, prioritized, and implemented. In addition, the change manager must ensure that all changes are communicated to the user community. The change manager must also work closely with the full life-cycle team to ensure that there is a complete understanding of the change being requested and that it is effectively implemented. In addition, the change manager must compare requested changes with the overall scope of the system to ensure that the system is evolving in accordance with the purpose for which the system was developed. If a requested change is not part of the overall scope of the system, the change manager will work with the client to determine if the scope needs to be updated or if the change should be rejected.

When a change to the system is requested, the change manager will identify the change as an enhancement, defect, or requirements issue. The change manager will then forward the change to the appropriate team. For example, if the change is an enhancement, the change manager will forward the issue to the requirements team who will work with the client to detail their enhancement requirements. Once the enhancement is fully understood, the original requirements document will be updated to include the new information and this new version will be forwarded to the developer and test team for review and implementation. If the change is a defect, the change manager will forward the issue to the testing team who will work with the development team to identify the defect and determine what functionality conflicts with the original requirement. The change manager will also work with the test team to ensure that all changes have been implemented correctly. The test team will verify all new requirements and will re-test defects to ensure that they have been addressed. Finally, the change manager will communicate the changes to the user community.

The change manager plays a very important role in ensuring data quality because they work directly with the user community to ensure that the users have the data they need to support their business requirements and to make accurate business decisions. As the data needed to make decision evolves, the change manager works with the user community to identify changes, with the project team to ensure that the changes are implemented and communicated to the user community.

User Support

The role of the user support or Help Desk team is to clarify user questions and issues. The goal of the user support team is to accurately respond to all user issues and ultimately to support the building of a knowledgeable user community that understands how the system functions meets their business needs.

The user support team will play a role very similar to the training team in that they must work closely with all other teams throughout the life-cycle process to ensure that they understand the scope of the system, the requirements and business needs driving the development of the system, how requirements were implemented during development, and how requirements were verified through test. In addition, the user support team will work closely with the testing team to understand any defects that may exist in the system, when they will be fixed, and if there is a "work-around" for the user. The user support team will also have to work with the change manager to understand any changes that are planned in an upcoming system release or that recently have been made to the system in order to answer any questions from confused users about new or planned functionality.
Once a system is implemented, the user support team, with help from the client, will determine the extent the user support team will be available to the users. For example, some user support teams provide around the clock support whereas other teams will provide only a few, set hours of support a day. In addition, the user support team will work with the client to determine what methods the users will adopt to communicate with the user support team and what methods the team will use to respond. Phone, e-mail, and in-person visits are all potential options. Once the user support team is operational, they will address questions and issues as they are identified from the user community and either answer them directly, or forward them to another team member (i.e., tester, requirements, trainer) to answer. The user support team is responsible for following up on all issues to ensure closure and to ensure that the user was satisfied with the response they received. In addition, based on the question or issues the user support team received, they may recommend that documentation, standard operating procedures, or training sessions be updated to better address that particular issue.

The user support team will ultimately support data quality by ensuring users have an accurate understanding of how to get data into the system and how to get the data they need out of the system. In addition, the user support team provides the user with a contact point once the training team has finished training. Providing this point of contact will make the users feel supported and ensure there is a resource to answer any questions that may arise.

Effective management of information systems allows system owners and the user community to make informed decisions about which data is integral to the fulfillment of the organization's mission. A thoughtful examination of the workflow processes, user needs and available technology allow organizations to create systems that achieve a defined goal and report accurate information. Understanding the roles and responsibilities of the players involved in creating an information system is key to successful system implementation and maintenance. Only through effective management during requirements gathering, development, testing, user support, training and change management can the integrity of a system's data be protected.

DOE's QUALITY SYSTEM PROGRAM: COOPERATIVE DEVELOPMENT AND IMPLEMENTATION

Dave Bottrell, U.S. Department of Energy, Germantown, Maryland
Mary Verwolf, U.S. Department of Energy, Idaho Falls, Idaho

Abstract — Implementation of a Quality Systems approach to making defensible environmental program decisions depends upon multiple, interrelated components. Often, these components are developed independently and implemented at various facility and program levels in an attempt to achieve consistency and cost savings. The U.S. Department of Energy Office of Environmental Management (DOE-EM) focuses on three primary system components to achieve effective environmental data collection and use:

- *Quality System guidance, which establishes the management framework to plan, implement, and assess work performed;*
- *Standardized Statement of Work for analytical services, which defines data generation and reporting requirements consistent with user needs; and,*
- *A laboratory assessment program to evaluate adherence of work performed to defined needs, e.g., documentation and confidence.*
- *This paper describes how DOE-EM fulfils these requirements and realizes cost-savings through participation in interagency working groups and integration of system elements as they evolve.*

Introduction

The Office of Safety, Health and Security (EM-5) within the DOE Office of Environmental Management (DOE-EM) is responsible for establishing policy and guidance related to analytical service activities. These activities include systematic planning, sample collection and analysis, performance evaluation programs, data validation, and laboratory assessment. To support these activities at the DOE Headquarters level, EM-5 established the Data, Decision, and Documentation (3D) Program. The 3D Program enables DOE Field and Program Offices to increase value and reduce risk from the $300-$600 Million spent annually on environmental data collection required to support decisions regarding health and safety, environmental restoration, packaging, waste management, stewardship, and transportation. Within this general mission, the 3D Program works cooperatively with internal and external organizations to improve regulatory and internal program acceptance and to leverage DOE-EM technical and management resources. To meet these broad objectives, DOE-EM, through the 3D Program is working to develop policy, guidance and tools to establish the required components of a cost effective and technically sound Quality System. In cooperation with the DOE National Analytical Management Program (NAMP), external federal organizations and Field Office contacts, the 3D Program has developed products in three specific areas: Quality Systems guidance, standardized laboratory contracting, and audit consolidation.

Quality Systems Guidance

Quality Systems are required by DOE Order 414.1 and other various regulatory drivers. Generally, these systems are based on ANSI/ASQC E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.* DOE-EM, through EM-5, participated as a consensus member of the Intergovernmental Data Quality Task Force which developed the *Uniform Federal Policy for Implementing Environmental Quality Systems (UFP).* The UFP outlines essential elements of a Quality System specific to managing environmental data collection and use and environmental technology programs. The development of the policy is a joint initiative among the U.S. Environmental Protection Agency (EPA), the Department of Energy (DOE), and the Department of Defense (DoD). The objectives of developing a policy which applies to all federal environmental programs are to address real or perceived inconsistencies and /or deficiencies with current environmental data collection practices and to improve processes to generate environmental data of known, documented quality that is suitable for the intended use. The benefits of consistent Quality Systems across federal agencies include:

- Improved effectiveness of federal environmental programs by focusing on results, quality of data and services, and customer satisfaction;

- Clarification of roles and responsibilities in managing and overseeing environmental data and environmental technology programs;

- Sufficient confidence in the systems such that duplication of oversight efforts are minimized; and,

- Enhanced accountability and public confidence in environmental decisions.

The EPA Office of Solid Waste and Emergency Response is adopting the UFP and has provided a written request to DOE-EM to join the EPA and DoD in implementing a Quality System consistent with the UFP. This document was issued by the Assistant Secretary of Energy for Environmental Management to the DOE complex as publication DOE/EM-0556 in January 2001. DOE site operations personnel are reviewing current data collection and use practices to achieve consistency with UFP requirements.

Standardized Laboratory Statement of Work (SOW) for Analytical Services

Historically, procurement of laboratory services has been conducted at the site level through the local Sample Management Office or through individual projects. This approach necessitated the development of site-specific performance criteria and solicitations for commercial analytical services. In spite of the fact that DOE-EM is one of the largest federal buyers of testing services, this buying power was not being leveraged at the national level. Additionally, the lack of complex-wide performance criteria contributed to redundancy in auditing and other quality assurance activities. Although the necessity to address site-specific internal and regulatory requirements is basic to analytical services, most aspects of a technical statement of work are relatively consistent (e.g., standard radioanalytical protocols or EPA reference methods). Recognizing this fact, DOE embarked on efforts to streamline analytical services procurement through the development of a standardized complex-wide statement of work. To achieve this objective, an Integrated Contractor Procurement Team (ICPT) formed by DOE federal and contractor personnel developed a consensus model to standardize laboratory requirements. Through the use of a Basic Ordering Agreement (BOA) for analytical services, standard requirements and technical criteria are established. The system also has built-in flexibility, in that site-specific details may be added as dictated by regulatory requirement or other special concerns. This feature avoids the pitfalls of the "one size fits all" approach.

As a component of DOE-EM's Quality Systems, implementation of the Standard Statement of Work enhances quality and efficiency in the following ways:

- Value of consensus technical expertise provided by the ICPT and available to DOE's smaller facilities;

- Cost avoidance, improved quality, and process improvement from standardized auditing and shared reports provided by the consolidated audit program;

- An efficient mechanism to introduce specific quality improvements, e.g., participation and acceptable performance in external performance evaluation programs; and

- Simplified procurements because negotiating the basic agreement and multiple pre-award laboratory assessments are not necessary.

Approximately 20 commercial laboratories have entered into the BOA with DOE sites. The approach has proven effective, and DOE is considering the development of requirements for radiobioassay and industrial hygiene testing services. This broadened scope will allow DOE to further leverage its buying power while at the same time enhancing data quality through the standardization of technical requirements and performance criteria.

Environmental Management Consolidated Audit Program (EMCAP)

Commercial analytical laboratories provide the bulk of the testing data used by DOE-EM for critical environmental decision making. To ensure that these decisions are made with data that is of known, documented quality, virtually all DOE-EM Operations/Field Offices conduct laboratory audits. Historically, each Operations/Field Office performed laboratory audits according to site specific requirements. In some cases, audits of certain laboratories were conducted by multiple programs and contractors from the same DOE facility. This led to a redundant, and therefore costly, approach to auditing. These inefficiencies were documented by the DOE Office of the Inspector General (IG) in the report *"Audit of the Department of Energy's Commercial Laboratory Quality Assurance Evaluation Program (DOE/IG-0374)."* This report also highlighted that DOE had not established uniform criteria for the evaluation of commercial laboratories. To address these issues, a working group was formed with the goal of developing a consolidated audit program. The Environmental Management Consolidated Audit Program (EMCAP) was initiated in early 2000 and is based on procedures and audit checklists developed through the evaluation of each site-specific audit program. We combined the most effective features of each site's activities to form the basic structure. Representatives from multiple DOE sites conduct EMCAP audits. The DOE complex, laboratories, and potentially stakeholders share audit reports and corrective action plans via a web-based data system. The main objectives of the program are to:

- Determine laboratory ability to generate and document data that is technically defensible and consistent with defined requirements;

- Facilitate sharing of audit results across the DOE complex and potentially with regulators to reduce program costs and potential risk from use of unacceptable laboratory data; and,

- Avoid unnecessary costs and improve the value of laboratory audits through establishing a consistent, controlled process.

EMCAP is managed by the DOE Oak Ridge Operations Office. In FY 2000, the program completed 19 audits, with over 40 currently scheduled for FY 2001.

Cost Benefits of Quality Systems Implementation

Although continuous improvement is the primary focus, implementation of complex-wide quality initiatives such as the Standard Statement of Work and the Consolidated Audit Program avoid unnecessary costs and program delays. In the case of the standardized statement of work, we avoid or minimize administrative and technical procurement resource requirements. For example, The DOE Oak Ridge Operations Office estimated their one-time savings from avoiding costs for contract administration at $150,000. The DOE Oakland Operations Office saved 2-3 months of technical and administrative time for one contract through the BOA but did not estimate specific costs.

EM-5 recently completed a study to evaluate relative costs for various contract mechanisms. The data suggest Basic Ordering Agreements achieve lower analytical service costs (30%) than achieved by fixed unit Indefinite Delivery Indefinite Delivery contracts. Three Office of Closure facilities (Rocky Flats Field Office, Ohio Field Office, and Oak Ridge Operations) that have actively worked to standardize and implement an analytical services Statement of Work have achieved the lowest cost analytical services across DOE.

DOE-EM is in the process of estimating projected and actual cost saving from the consolidated audit program. An inherent difficulty is identifying the number, type, and cost of the audits of environmental laboratories conducted by EM. The previously cited Inspector General Audit (DOE/IG-0374) reported that 50% of DOE's audits of commercial laboratories were redundant (103 of 206). This percentage could escalate because the laboratory community is becoming more competitive and shrinking, i.e., the DOE complex has fewer laboratories to consider, increasing potential for redundancy. For example, if certain laboratories recognized for high technical quality were audited by six Field Offices, excess costs of > $50,000 per commercial lab (5 redundant audits X $11,500/audit) would be incurred. In FY 2000, 87 audits were identified and nearly half were redundant ($400,000 unnecessary cost). As described earlier, the EMCAP will meet current audit needs of participating Offices with less than 50 audits (compared to >200 audits historically performed). This represents a cost avoidance > $1 million and likely approaching $2 million. The primary audit costs are time and travel which are both optimized by utilization of audit teams that are in the same geographical area as the laboratory, a situation impossible in the case of site-specific audits.

Conclusion

The Department of Energy, including the Office of Environmental Management, is committed and mandated to maintain a Quality System solution to facilitate, document and defend environmental decisions. This paper focuses on the Quality System infrastructure and specific programs to define laboratory requirements and assess adherence to these requirements. The DOE Standard Statement of Work and Consolidated Audit Program are two elements that have recently reached an implementation phase. More information on participation, contacts, and specific audit materials may be found on the Internet at http://www.em.doe.gov/safetyhealth/3d/.

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THE RADIOCHEMIST'S ROLE IN THE QUALITY EVALUATION AND ASSESSMENT OF RADIOLOGICAL DATA IN ENVIRONMENTAL DECISION MAKING[1]

Svetlana Bouzdalkina, Research Institute of Radiology, Gomel, Republic of Belarus;
Raymond J. Bath Ph.D.,* US DOE/Environmental Measurements Laboratory, NY, NY;
Pamela D. Greenlaw, US DOE/Environmental Measurements Laboratory, NY, NY; and
David Bottrell, US DOE/EM5, Germantown, MD.

Abstract — The quality evaluation and assessment of radiological data is the final step in the overall environmental data decision process. This quality evaluation and assessment process is performed outside of the laboratory and generally the radiochemist is not involved. However, with the laboratory quality management systems in place today, the data packages of radiochemical analyses are frequently much more complex than the project/program manager can effectively handle and additionally with little involvement from radiochemists in this process the potential for misinterpretation of radiological data is increasing.

The quality evaluation and assessment of radiochemistry data consists of making three decisions for each sample and result remembering that the laboratory reports all the data for each analyses and additionally the uncertainty in each of these analyses. Therefore at the data evaluation and assessment point the decisions are: is the radionuclide of concern detected (each data point always has number associated with it); is the uncertainty associated with the result greater than would normally be expected; and if the laboratory rejected the analyses is there serious consequences to other samples in the same group. The need for the radiochemist's expertise for this process is clear. Quality evaluation and assessment requires the input of the radiochemist particularly in radiochemistry because of the lack of redundancy in the analytical data. This paper will describe the role of the radiochemist in the quality assessment of radiochemical data for environmental decision making.

Introduction

The goal of the environmental data collection process is to produce quality, credible and cost effective data to support the decision making process. The data collection process can be divided into the stages of planning, sampling, analysis, verification, validation, assessment and use (figure 1). Even though for the determination of radionuclides in the environment, these stages have unique requirements,

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radiochemists are not usually involved in any of the stages except the laboratory analysis. The reasons for the lack of radioanalytical support are complex but usually since the evaluation and assessment of radiochemical data is performed outside of the laboratory, input from the radiochemist is not available. With the laboratory quality management systems in place today, the data packages of radiochemical analyses are frequently much more complex than the project/program manager can effectively handle and without radiochemist support the potential for misinterpretation of radiological data is increasing.

Radiochemistry data is distinctly different from all other analytical analyses since each measurement always; 1) results in a number, 2) each measurement has an associated uncertainty, and 3) each measurement is reported with an MDA (minimum detectable activity). In order then for a quality evaluation and assessment of this type of data to be accomplished three distinct decisions must be available for each sample result. They are: 1) Is the sample result greater than background? 2) Is the uncertainty in the sample result normal? and 3) Is the sample result so uncertain that the data point must be rejected?. These distinct analytical decisions can be provided throughout the entire data collection process if the program manger utilizes input from the radiochemist. This paper demonstrates the role for the radiochemist in all the stages of the environmental data collection process and demonstrates that role for a quality evaluation and assessment of radionuclide data.

The Environmental Data Collection Process

An efficient environmental data collection activity depends on a series of well thought out logical steps. These steps address what data need to be collected and how the collected data will be assessed for usability to support the decision making process. For radiochemical investigations, more emphasis is placed on the individual determination. It should be emphasized that the integration of a chemist at each step is essential for quality use of the data. The data collection activity presented here is in stepwise sessions for ease of illustrating the chemist's role in the data collection process and is not meant to be a full treatise on the entire process. The chemist role in each step is described below.

The process begins with a directed planning step which assures that sufficient planning is carried out to adequately define a problem, to determine its importance and to develop an approach to solutions prior to spending resources. Essentially each process presents a stepwise approach that includes a planning, implementation and assessment phase in each stage. These stages are all interconnected so that the assessment phase of one step is in reality the first part of the planning phase of the next step. These interconnected steps will allow a complete environmental data collection program to emerge that will meet the program needs and in effect be the "quality evaluation and assessment" of the program.

1) Directed Planning

The directed planning is the foundation of the data collection process. This planning process follows the Data Quality Objectives (DQO) program. The radiochemist should participate in the initial planning for the project to offer input on the adequacy of existing radiological data to determine need for further sampling, radionuclides of concern and expected concentrations. The chemist insures that the proper radionuclides are selected, Measurement Quality Objectives (MQOs) are clearly defined, methods of analysis are adequate and meet the objectives, and that the number of sample results will enable the program manager to meet the stated goals of the process.

The radiochemist role includes developing an appropriate quality system that is capable of implementing the quality controls and the quality assurance necessary for success. The quality assurance system will oversee the implementation of Quality Control (QC) samples, documentation of QC sample compliance or non-compliance with MQOs, audits, surveillances, performance evaluation sample analyses, corrective actions, quality improvement and reports to management. The documentation generated by these quality assurance activities and their outputs during project implementation will be a key basis for subsequent assessments and data usability decisions

2) Sampling

Sampling includes all the activities up to and including the taking of a sample for shipment to a laboratory. The radiochemist provides input for contract negotiations, sample design and sample handling including sample preservation, sample container requirements, compositing, and subsampling. The radiochemist prepares the Statement of Work for the laboratory analyses including the Limits of Detection, sampling and laboratory quality control activities, and all required data deliverables.

3) Analysis

Analysis includes all the activities that will result in the production of the data package.
The radiochemist role is to provide input to all of the activities from the field Chain of Custody to analysis quality control activities to final data output. The radiochemist provides a quality oversight role that includes review and consultation on methods used especially for development and approval of a performance base measurement system (PBMS), instrument calibration, laboratory and matrix interferences, etc.,. The radiochemist should be in communication with the program manager and be responsible for any changes required by the program.

The last three steps in the data collection process are collectively known as the assessment phase. These steps all require a radiochemist expertise. The radiochemist role should include technical input to Verification and Validation steps and support for data Assessment to insure that the data meets the needs of the program.

4) Verification

Verification assures laboratory conditions and operations were compliant with the statement of work (SOW) and project plan documents. The chemist role is to verify the data package delivered by the field or laboratory meet requirements (compliance) that were outlines in planning, checks for consistency and comparability of the data throughout the data package, the QC parameters were with in limits, the correctness of basic calculations, data for basic calculations, and completeness of the results to ensure all necessary documentation is available. The primary function of the radiochemist should be to apply appropriate feedback to the laboratory resulting in corrective action or recommending that the project planning process be revisited.

5) Validation

The validation of the data addresses the issues of reliability and uncertainty of the data. The role of the radiochemist is to provide input from a review of the verification report and laboratory data package to identify its areas of strength and weakness and to provide the application of qualifiers to the data. These qualifiers reflect the impact of not meeting the MQOs and can result in the entire data set be send back through the planning process.

The radiochemist has a unique role in the validation process by being able to evaluate the data to determine the presence or absence of a radionuclide, and the uncertainty of the measurement process. During this validation, the technical reliability and the degree of confidence in reported analytical data are presented.

6) Assessment

Assessment is the last phase of the data collection process, and consists of a scientific and statistical evaluation of project-wide knowledge to assess the usability of data sets. The Radiochemist compares the data produced with the planning documents and any other analytical process requirements that were developed in the planning process. To assess and document overall data quality and usability, the chemist assists the data quality assessor to integrate the validation report, field information, assessment reports, and historical project data, and compares the findings to the original project planning documents. The DQA process uses the combined findings of these multi-disciplinary assessments to determine data usability for the intended decisions, and to generate a report documenting usability and the causes of any deficiencies. It may be useful for a validator to work with the assessor to assure the value of the validation process (e.g., appropriateness of rejection decision), and to make the process more efficient

The assessment of data requires the input of a radiochemist in terms of sampling and analytical MQOs, QC sample data (*e.g.*, % yield) and compliance with specifications and requirements (*e.g.*, required combined standard uncertainty). If these records are missing or inadequate, then compliance with analytical protocol specifications, including the MQOs which were identified during the planning phase, will not be ascertainable and will raise questions regarding quality of the data.

7) Use

The radiochemist role in the development of these steps during the directed planning process will increase the likelihood that the appropriate documentation will be available for regulatory and other program related activities. Documentation and record keeping during the environmental data collection process is essential to subsequent data verification, data validation, and data quality assessment. Thorough documentation will allow for a determination of data quality and data usability objectives.

It is important to note that the radiochemist is uniquely qualified to perform the technical roles in the environmental data collection process. Radiochemists will provide expertise in radiation/nuclide measurement systems and the knowledge of the characteristics of the analyte of concern to evaluate their fate and transport. The radiochemist will also provide knowledge about sample transportation issues, preparation, preservation, sample size, subsampling, available analytical protocols and achievable analytical data quality. The use of a radiochemist will ensure the effective use of resources available to the project.

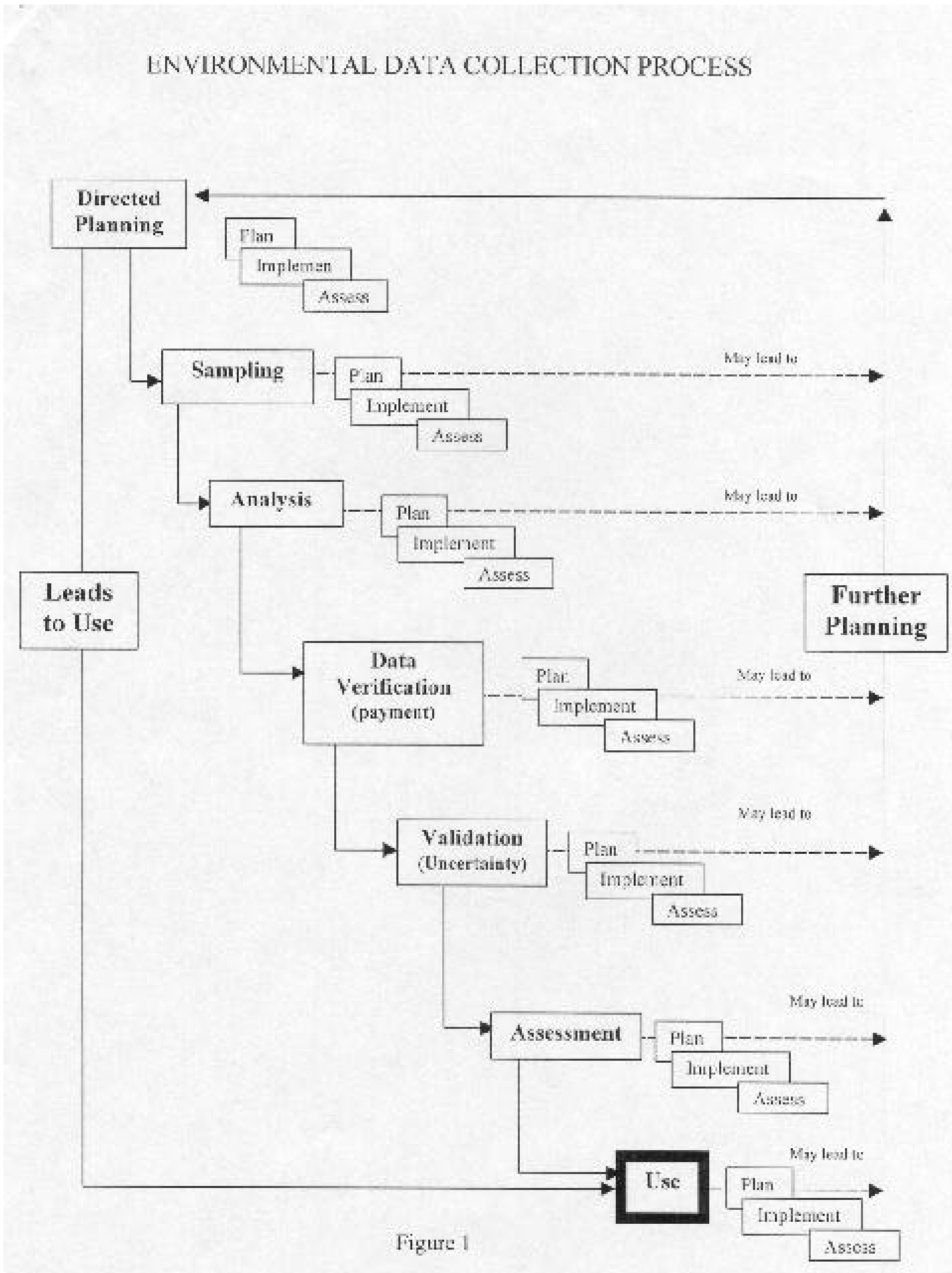

Figure 1

RAISING THE CURTAIN ON THE GRAY REGION

Cliff J. Kirchmer, Agency QA Officer, Environmental Assessment Program
Washington State Department of Ecology

Stewart M. Lombard, Program QA Coordinator, Environmental Assessment Program
Washington State Department of Ecology

Abstract — The gray region in EPA Document QA/G-4 is defined as the range of possible parameter values near the action level where the cost of determining that the alternative condition is true outweighs the expected consequences of a decision error. EPA Document QA/G-4HW clarifies that during the planning stage the action level is based on an ideal decision rule, while during the assessment stage an operational decision rule is used.

This paper analyzes the factors that define the gray region and the action level, including the errors of the first kind (a) and second kind (b) and the number of samples taken to determine the mean result. The relationship between the Decision Performance Curve presented in EPA QA/G-4 and the statistical power curve is also discussed. The statistically derived critical level is identified as the concentration of importance for decision-making. The action level is defined in terms of the critical level so that its value is consistent for decisions made during both planning (a priori decisions) and assessment (a posteriori decisions).

This paper is a result of our effort to understand the statistical basis for the Decision Performance Curves and Decision Performance Goal Diagrams described in EPA documents QA/G-4 and QA/G-4HW. The Decision Perfomance Goal Diagram, which approximates the Decision Performance Curve, is presented by EPA as a means of stipulating your tolerable risks of decision errors and communicating them to others.

Figure 1 is an example of a Decision Performance Curve (DPC) which is in both QA/G-4 and QA/G-4HW. Both an ideal DPC and a realistic DPC are illustrated. The ideal DPC corresponds to the probabilities of decisions made if there were no random error and the realistic DPC corresponds to the real world situation where decisions must be made against a smokescreen of random error. It is assumed that systematic error (bias) has been controlled and only random error is considered in decision-making. It is important to note that the Action Level specified in Figure 1 corresponds to the idealistic DPC. The Action Level is defined as being either fixed standards (e.g. drinking water standards or technology-based standards) or investigation-specific (e.g. background standards or specific risk-based standards). In the real world, because of random error, one cannot have realistic action levels set equal to the standards.

Thus, it must be understood that the Action Level identified in Figure 1 is to be used only in the planning stage when considering an ideal DPC. This can be a source of confusion if one identifies the ideal Action Level used during project planning with the realistic Action Level that must be used during project assessment.

Figure 2 is an example of a DPC overlaid on a Decision Performance Goal Diagram (DPGD), taken from EPA QA/G-4HW. A DPGD is a graphical representation of the tolerable risks of decision errors, and is used in conjunction with a Decision Performance Curve. DPGDs, like DPCs, are planning tools and specify theoretical Action Levels, which can also be a potential source of confusion.

The DPGD includes a gray region. One boundary of the gray region is located at the action level based on the theoretical decision rule and the other boundary is located at the true concentration value at which the consequences of a false acceptance decision error are considered significant enough to set a limit on the probability of it occurring.

EPA's approach to specifying tolerable limits on decision errors and the subsequent assessment of the data provide good mechanical step-by-step procedures that do not require a detailed understanding of statistics. But for some, an understanding of the statistical basis for decision-making, including the differences between action levels during planning and assessment phases and the meaning of the gray region and its boundaries, may help to give more confidence in the process.

To understand the use of DPCs as planning tools, it helps to understand that each point on the curve corresponds to a true value for the parameter, and that each true value can be thought of as having an associated underlying population distribution.

Similarly, the boundary values of the DPGDs have associated underlying population distributions. Recognition of these underlying population distributions can help to understand the meaning of the gray region. The population distributions associated with the true values at the boundaries of the gray region are of particular importance in understanding decision errors.

Figure 2 corresponds to the baseline condition where the parameter exceeds the action level. In the case of site cleanup, this could be described as a baseline condition of "The Site is Dirty". From a statistical point-of-view this can be understood as corresponding to a null hypothesis that the parameter equals the Action Level (H_O: μ=A.L.) with the alternative hypothesis being that the parameter is less than the Action Level (H_A: μ<A.L.). These hypotheses can be depicted as normal distributions of the parameter with means equal to the boundary values of the gray region.

Figure 3 shows these normal distributions side-by-side. The null hypothesis is represented by a normal distribution with a mean of 100 and the alternative hypothesis is represented by a normal distribution with a mean of 80. The false acceptance decision error rate of 0.05 (type II, *b*) and the false rejection decision error rate of 0.05 (type I, *a*) are also shown. The *a* and *b* values in Figure 3 are the same (0.05), while in Figure 2, *a*=0.05, but *b*=0.1. The values represented on the distribution curves are not the true values, but rather the estimated probability of obtaining those values for the population under study when the true values are either 80 or 100.

During planning, in addition to needing an estimate of the population standard deviation for individual results, decisions must be made regarding tolerable false acceptance and false rejection decision error rates, as well as the minimum detectable difference (equal to the width of the gray region). These planning decisions will determine how many samples need to be taken, analyzed, and averaged to obtain a result. This is an iterative process, since cost also needs to be taken into account. The first estimate of the number of samples needed may exceed the available budget, and in that case a compromise will need to be made regarding the tolerable decision error rates and minimum detectable difference in order to lower the cost of sampling.

As Figure 3 illustrates, during assessment only the false rejection error (a) is used for deciding whether to reject the null hypothesis (e.g. in the case of site cleanup, to reject the null hypothesis that the site is dirty). The decision point for the chosen value of a is called the critical level. As an alternative to designating the Action Level at the same concentration as the standard being used, one could designate the critical level as the Action Level. The critical level would be estimated during the planning stage based on the estimated standard deviation and chosen levels for a, b and the minimum detectable difference (gray region). During the assessment stage the critical level would be calculated based on the t-test, using the data obtained during project implementation. The advantage of this approach would be to have a consistent Action Level during planning and assessment, avoiding the need for theoretical and operational Action Levels.

The gray region depicted in Figure 2 corresponds to the region between the means of the distributions in Figure 3 (i.e. between 80 and 100). EPA defines the gray region as the range of possible parameter values near the action level where the cost of determining that the alternative condition is true outweighs the expected consequences of a decision error. The gray region is also described as a range of true parameter values within the alternative condition near the Action Level where it is "too close to call". This may have some meaning during the theoretical planning stage. But during the realistic assessment phase, as can be seen in Figure 3, the critical level where the call must be made is located within the gray region. Again, this can lead to confusion if one believes that assessment decisions cannot or should not be made for results found in the gray region.

From the perspective of planning, enough samples are taken to reduce the probability of a false acceptance to a tolerable level, but one can never be certain that a false acceptance (or false rejection) error has occurred. For the sampled data, the critical level is located within the gray region, and corresponds to the concentration that must be used during assessment to make the call as to whether to accept or reject the null hypothesis. We would rather not get results in the gray region but, if we do, we want the power of the test to be at a level that will give confidence to our decision.

From a planning perspective, the boundaries of the gray region (minimum detectable difference in statistics) are important, since they are needed to determine how many samples must to be taken, analyzed and averaged in order to achieve the chosen decision errors for acceptance and rejection. Another way to express this is that if the true value is equal to the left boundary value in Figure 2, the probability of correctly rejecting the null hypothesis (i.e. concluding that the site is clean) is equal to $1-b$, which is the statistical "power" of the test to detect an effect (i.e. for Figures 1-3, that the concentration is less than the standard level).

Decisions can be thought of as being "*a priori*" or "*a posteriori*", depending on whether they are made during planning or during assessment. Both a and b errors must be taken into account for "*a priori*" decision-making, while only the a error needs to be addressed for "*a posteriori*" decision-making.

There are some advantages to identifying the action level as being at approximately the same concentration level during planning and assessment. ASTM document D5792-95 achieves this by identifying an operational decision rule rather than an ideal decision rule. Figure 4 shows a Decision Performance Curve taken from ASTM D5792-95, in which the Action Level is located at a concentration where the probability of taking action is 0.5 (i.e. b =0.5) and is distinguished from the Regulatory Threshold (EPA's theoretical Action Level). The plot of Figure 4 is for Possible True Concentrations rather than the True Values of the Parameter plotted on Figure 1. An even better description would be to identify the Action Level on Figure 4 as a value obtained from sample data.

The DPC (and DPGD) are prepared during the planning phase. EPA defines the DPC as a power curve (or a reverse power curve depending on the hypothesis being tested). A power curve in statistics is a plot of 1-b vs. the true value. Figures 1 and 4 are reverse power curves, since they are plots of b vs. the true value, corresponding to the probability of deciding that the parameter exceeds the Action Level using sampled data. A power curve is a mirror image of Figures 1 or 4 and corresponds to the "*a priori*" probability that one will detect an effect (i.e. reject the null hypothesis) for different values of the true concentration. The power curve may provide some additonal insight to decision-makers that is not provided by the DPC or reverse power curve. A DPGD analogous to a power curve could be constructed by deciding what probability of rejection of the null hypothesis or baseline condition is desired at a given "*a priori*" concentration (corresponding to the left side of the gray region or minimum detectable difference). These and other considerations will be discussed during the presentation.

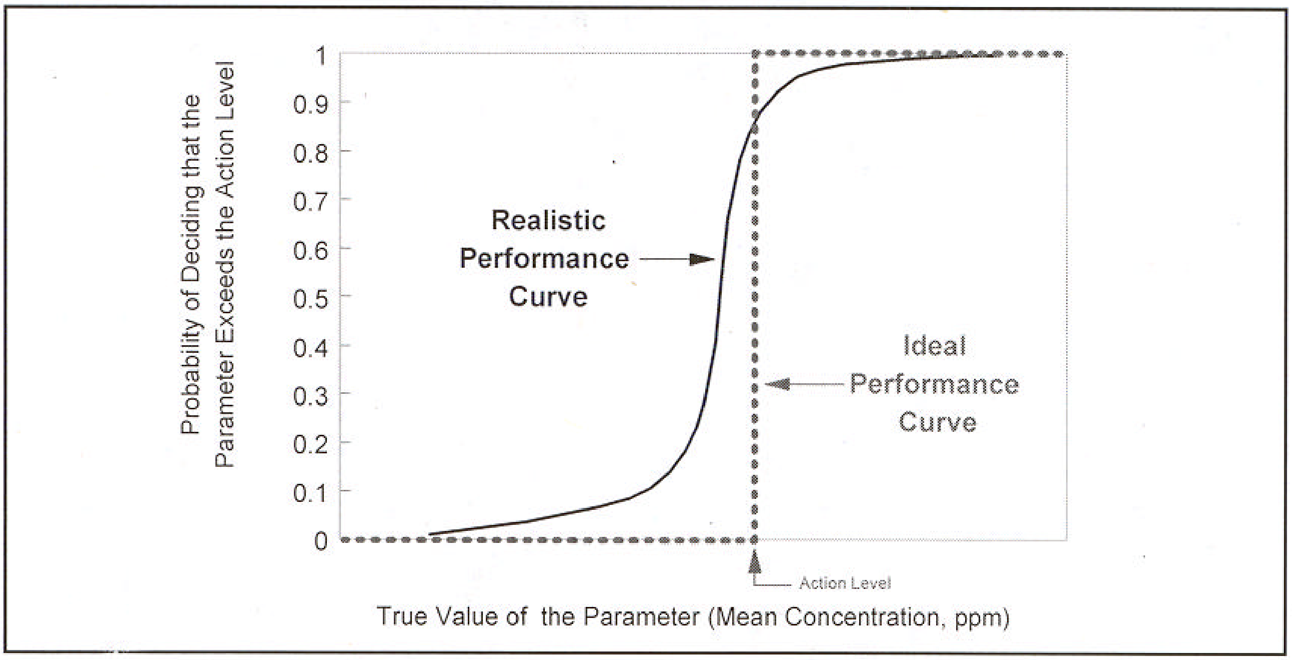

Figure 1. Ideal Versus Realistic Performance Curve

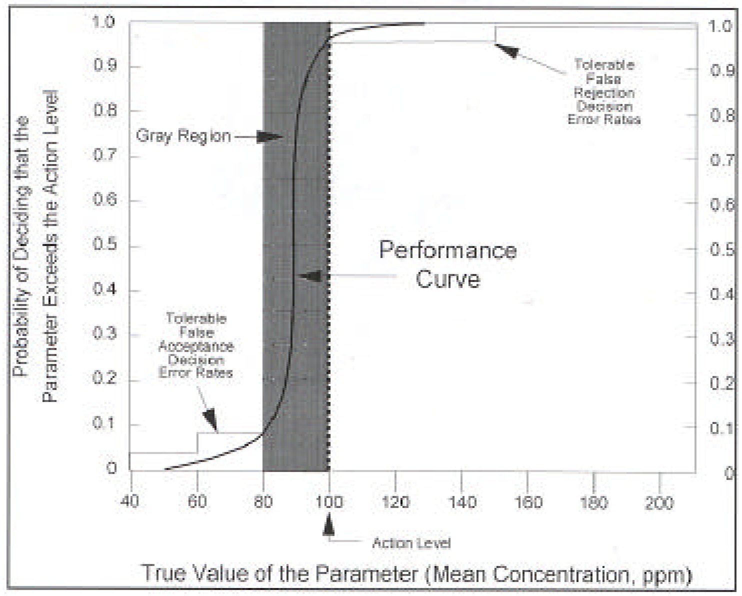

Figure 2. An Example of a Performance Curve Overlaid on a Decision Performance Goal Diagram (Baseline Condition: Parameter Exceeds Action Level)

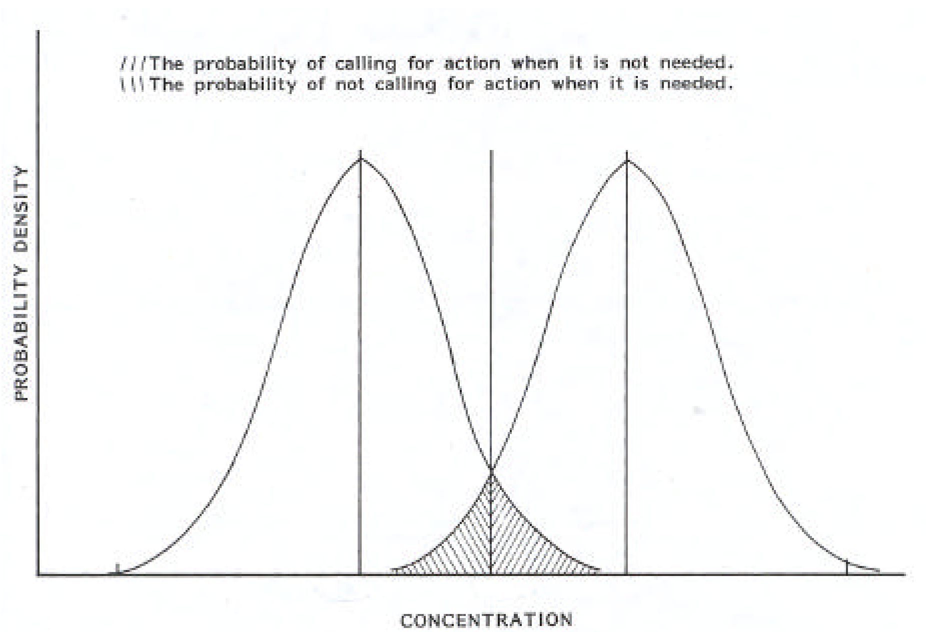

Figure 3. Statistical approach to quality control

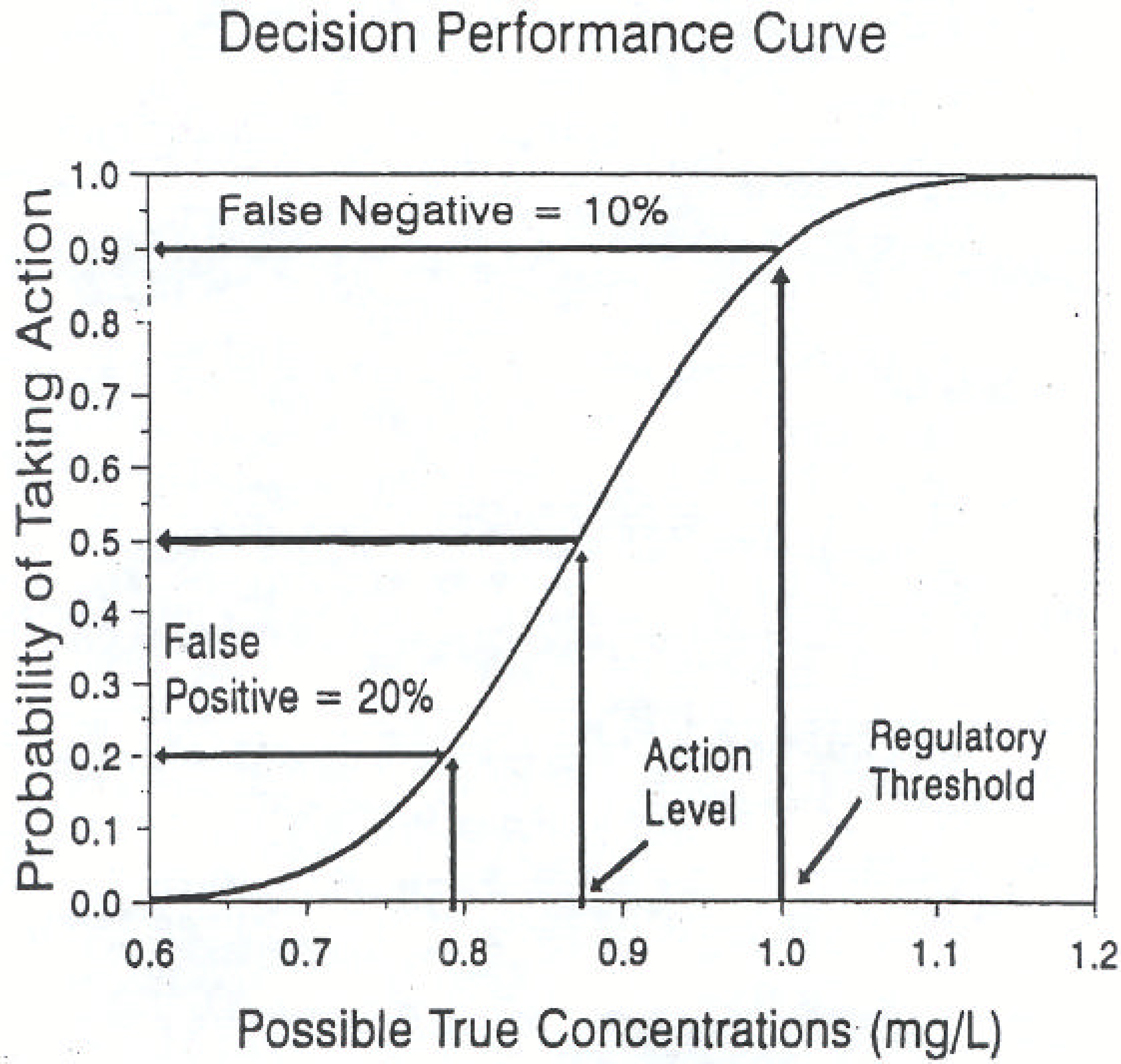

FIG. Decision Rule Development

Figure **Figure 5**

QUALITY ASSURANCE PROJECT PLANS FOR SURVEYS

Malcolm J. Bertoni, Research Triangle Institute

Abstract: When the U.S. EPA recently revised its administrative Order 5360.1, which establishes the authority and scope of the mandatory EPA Quality System, it clarified that the Quality System applies to a broader set of data collection activities than previously had been acknowledged. In addition to traditional environmental measurements, the Order now clearly encompasses "the use of environmental data collected for other purposes... including literature, industry surveys, ..." and a wide range of modeling, information management, and environmental technology activities. This paper addresses quality assurance planning for surveys by examining how EPA requirements for Quality Assurance Project Plans (QAPPs) can be interpreted for data operations involving questionnaires and interviews. Quality assurance professionals who may discover that they are now responsible for developing or reviewing QAPPs for survey projects may find this topic helpful. EPA continues to conduct many national surveys to obtain information about regulated industry compliance costs and operations, as well as for other purposes. Often these data are collected through survey questionnaires administered in a variety of ways, such as traditional mail-out self-administered paper questionnaires, face-to-face "pen-and-paper interviews," and computer-aided telephone interviews. The survey profession has developed a sophisticated set of quality assurance practices to assure the validity, reliability, accuracy, and integrity of survey data. These practices fit reasonably well into the framework of required elements set forth in EPA Requirements for Quality Assurance Project Plans (QA/R-5), although some interpretation is necessary. This paper discusses the different kinds of issues that arise in survey projects, using as an illustrative example the U.S. EPA Office of Ground Water and Drinking Water's 2000 Community Water System Survey, a national survey of drinking water utilities to obtain cost and operational information that will support drinking water regulation development. The paper will discuss the importance of systematic planning and the development of performance and acceptance criteria; special issues arising from the need to validate survey instruments; human subjects protections and confidentiality issues; common survey data reduction and processing requirements; data management challenges; and other survey quality management issues that may not be familiar to quality assurance professionals who work on traditional measurement data collection projects. The paper will also discuss the relationship between QAPP elements and the requirements for Information Collection Requests, which the Office of Management and Budget must review and approve before most surveys can be authorized to proceed. Finally, some quality issues associated with new survey technologies, such as computer-assisted interviews and Internet-based instruments will be explored.

AUTOMATED DATA REPORTING AND REVIEW TO ENSURE DATA QUALITY AND IMPROVE PRODUCTIVITY

Bart Simmons and Jianwen She
Hazardous Materials Laboratory, Department of Toxic Substances Control, CalEPA
2151 Berkeley Way, Berkeley, CA 94704

As a state analytical laboratory, Hazardous Materials Laboratory (HML) has various analytical instruments with quite different data processing and report tools that generate varied report formats and contents. Development of an organization-wide report protocol, automatic report generators, and report reviewing software has become a very important aspect of the laboratory QA program. Since our sample and test information are stored in a minicomputer based LIMS, and analytical results are stored in different platforms with different data format, manual reporting was the only approach at the laboratory before this work. Transcription errors and loss in productivity are two major shortcomings of manual reporting.

To improve our quality system and productivity, HML started to standardize and automate its report processes using Microsoft Excel and Access. Both Excel and Access are familiar to most laboratory chemists and both programs can be automated using the same powerful programming tool ---Visual Basic for Application (VBA).

The use of organization-wide report protocols and the automatic report generators will substantially reduce costs and eliminate human error. This will also allow consistent reporting practices to be adopted in the laboratory and allow data reviewers/validators to focus and spend more time on inspection of raw data.

The goal of this work is to create a standardized, user friendly GUI report system which can access data from different platforms with different formats. We named the report system “HMLREP”. It was designed and implemented by laboratory chemists for chemists who do not need to have Excel or Access experience.

HMLREP can read various data formats, including data from Perkin Elmer LIMS, ICP-MS, ICP AES, GC, GC/MS and other calculation packages. It will automatically parse incoming data, populate corresponding data fields in the report template and check significant figures. Other features include checking flags, checking blank sample contamination and calculating the RPD for duplicate samples. HMLREP can also check wet-based, dry-based or fat-based report pages to make sure they are flagged correctly. HMLREP also keeps a unique series number for each report generated by program and provides an online help system for report generators and users. Based on different analytical methods, HMLREP can also check recovery and sample hold times to make sure the data meet laboratory QA requirement. It can calculate TEQs according to different TEF models in the dioxin report.

This presentation will show some programming techniques used for implementing HMLREP. Among them, form design, LIMS data access, instrument data transfer, significant figure control will be discussed. One inorganic and one trace analysis report generating example will also be presented.

A DATA QUALITY STRATEGIC PLAN FOR THE U. S. ENVIRONMENTAL PROTECTION AGENCY

Cindy Bethell, U.S. EPA

Since July 2000, a workgroup has been analyzing the Environmental Protection Agency's quality system processes to identify where data quality vulnerabilities exist. This paper highlights the factors that brought this workgroup together, the process used for the analysis, and the recommendations which have been submitted to EPA's Quality Subcommittee.

Introduction

Data and information are vital to informing public policy decisions and the regulations that help protect the nation's air, land, and water–the mission of the Environmental Protection Agency (EPA). Reliable information and data of documented quality also constitute a valuable resource for the public and leaders across society who increasingly demand access to accurate environmental information that is comparable and complete.

In recent years, the Agency's data and data systems have come under increasing scrutiny from Congress, federal offices including the General Accounting Office (GAO), EPA's Office of Inspector General and Science Advisory Board, and the Office of Management and Budget, who assert the Agency's environmental data lack validity, consistency, and reliability.

Most of EPA's major data collections were initiated decades ago, prior to the current understanding of data quality principles and in the absence of the standards and metadata requirements that are vital to the reliability and secondary use of data. The vast majority of data used by the Agency is collected by state and local agencies, and the regulated community using inconsistent collection and analytical methodologies, identification standards, and documentation. The impact of this variability was noted in a February 2000, GAO report stating that, due to unreliable data, the Agency is unable to give an accounting of the environmental health of the nation's water bodies.[1] The report cited several causal factors, including inconsistencies in water body assessments and methodologies, lack of standards and common definitions, and questionable data consistency and reliability.

EPA's new information office, the Office of Environmental Information (OEI) was established in October 1999. Since that time numerous separate inquiries regarding the state of the Agency's data quality were sent to OEI from Senators Bond, Smith, Baucus and House Committee Chairmen Fowler and McIntosh, and others. EPA's data quality and completeness are squarely on their radar screen and the new office has raised expectations that the issue of data quality will receive greater attention from EPA. In March 2000, Margaret Schneider, Principal Deputy Assistant Administrator for OEI, testified before the House

[1] Managing for Results: Challenges Agencies Face in Producing Credible Performance Information (February 2000, GAO/GGD-00-52)

Subcommittee on Oversight, Investigations and Emergency Management, Committee on Transportation and Infrastructure, to answer questions on the quality of the Agency's data, and in a follow-up request from the House Subcommittee a data quality assessment was requested for four EPA data systems. The assessment was completed and a report submitted in August 2000.

The Data Quality Strategic Plan

The Quality and Information Council, the Agency's senior-management body for setting information and quality policy, is assisted by four subcommittees. One is the Quality Subcommittee, which in July 2000, formed a cross-Agency workgroup to develop a Data Quality Strategic Plan (DQSP). The Subcommittee's charge to the Workgroup was first to identify where and how to improve the quality of the Agency's *environmental* data and second, to recommend how to improve the *quality culture* at EPA; to further embed an appreciation for the role and importance of quality assurance at all levels.

What is Quality?

Understanding and assessing data quality is matrix-like in complexity, where the x-axis represents different *types of data* (regulatory compliance, permitting, violations, ambient concentration measurements, geo-spatial, laboratory analysis, monitoring, technology performance data, etc.) and the y-axis represents different *types of quality* along the entire data life cycle from planning to sample measurement, analysis, assessment, through transmission, storage and reporting. At any given point on this x-y grid, the notion of quality will take on different meanings.

The conventional wisdom among EPA's data detractors and among some EPA staff, appears to be that in general, the Agency's data is unreliable. This view is part perception but also part substance. Because standard data quality assessments are not routinely performed on the Agency's data, we lack a quality baseline, and even standard quality criteria by which to determine the veracity of the conventional view. For those systems which have been recently assessed for "quality," the Toxic Release Inventory System and Safe Drinking Water Information System, for instance, the aspect of quality examined is primarily at the data system level. The questions answered are not, 'do the values accurately represent the actual pollutant release or ambient condition,' but rather, 'are the data in the data repository consistent and complete in comparison to the originating system or documentation?' While this back-end assessment of "quality" is of value, it says nothing about highly significant front-end stages of the data lifecycle.

EPA's major statutes and the programs they have spawned are very different in purpose and structure. Clean Air Act regulations and guidance are quite specific in their quality assurance requirements for ambient air monitor siting requirements, instrument precision testing protocols, and scientific rigor that underpins the entire monitoring program. The Superfund Program also has an effective quality management system and its data and analysis are generally of known quality. The same cannot be said for all EPA environmental data programs.

Methodology

Views and Reviews

The Workgroup analyzed reviews of EPA's data and information quality management, by oversight organizations such as the General Accounting Office, Science Advisory Board, National Academy of Public Administration, the Environmental Council of the States, and business groups such as the Business Roundtable and Coalition of Effective Environmental Information. Examples of their observations and advice follow.

The Science Advisory Board:[2]

- EPA's Quality System implementation is uneven and varies from organization to organization, increasing the likelihood of problems with data quality and the associated decisions;
- Over 75 % of states are generating data of unknown quality because they lack approved Quality Management Plans;
- Incomplete implementation of the Agency's Quality System precludes proper evaluation and produces the potential for waste, fraud and abuse;
- The reporting status of quality staff denies access to the proper level of authority and the independence necessary to oversee the Agency's services and products;
- The problem of access also exists at the regional, program and state levels;
- Senior managers needs to be a champion for successful implementation of the Agency's Quality System and need to implement a more complex web of persuasion, administrative mandates, and rewards.

In a March 2000, GAO reported that The National Water Quality Inventory, or 305(b) report on surface waters, is not a reliable representation of nationwide water quality conditions due to *incomplete and inconsistent data*, yet EPA uses this report for decision making because it is the only source on whether waters are meeting water quality standards.[3] No factual understanding of how well the Agency is achieving its mission to protect the nation's waters exists.

EPA's Office of Inspector General has identified various weaknesses in the Agency's quality system implementation and management, stating, "Without an effective Agency-wide program, EPA could not fulfill its mission" which depends on having environmental data of known and adequate quality.[4]

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[2] *Review of the Implementation of the Agency-Wide Quality System*, by the Quality Management Subcommittee of the Environmental Engineering Committee, Science Advisory Board, February 25, 1999.

[3] *Water Quality: Key EPA and State Decisions Limited by Inconsistent and Incomplete Data* (GAO/RCED-00-54).

[4] *EPA Had Not Effectively Implemented Its Superfund Quality Assurance Program* (E1SKF7-08-0011-8100240, September 30, 1998)

In the National Academy of Public Administration's November 2000 report, *Transforming Environmental Protection for the 21st Century*, four of ten recommendations apply to EPA's Quality System:

- Invest in Information and Assessment. "Develop objective data of high quality.
- Hold States Accountable For Results. "Redefine EPA's expectations of states in terms of environmental results rather than only process."
- Invest in Information. "Appropriate sufficient funds for major improvements in environmental data and in program assessment."
- Challenge EPA, Congress, and One Another to Transform Environmental Governance. "Build evaluation into the design of . . . programs."

The Business Roundtable (BRT) has developed their *Blueprint 2001*: *Drafting Environmental Policy for the Future*, which includes the following recommendations:

- EPA needs a more a disciplined focus on data quality and scientific rigor.
- Improve data collection, use electronic data collection and reporting, move toward integrated reporting, recordkeeping, and monitoring.
- The government should provide better information stewardship, policies that place environmental information in context, and tools for assessing its accuracy.

Sherwood Boehlert, chairman of the House Science Committee, has endorsed BRT's proposal to move to performance-based management and has promised the group to take a serious look at the proposals. Boehlert said:

> *Sound science is the key to reaching consensus on tough environmental problems, and technology is the key to affordably solving those problems.*[5]

Analytical Process

Building upon the observations and comments of external reviewers, the Workgroup developed a 12-step model to identify *where* along the data/information lifecycle, vulnerabilities to data quality exist and then identify ways to mitigate those vulnerabilities. The model spanned from planning for a data collection to ultimate storage in a data system. About 90 resulted from that exercise. The Workgroup next grouped this long list under five categories and developed white papers exploring seven key themes. Finally, interviews were conducted with managers, and data collectors or evaluators from all program offices and six regions–a total of 40 interviews–to better understand the view of decision makers regarding their use of data, quality priorities, and their expectations of the Data Quality Strategic Plan.

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[5] *Inside EPA*, February 23, 2001. Boehlert's comments were quoted from a February 8, 2001, briefing with the Business Roundtable.

Recommendations

The Workgroup developed seven sets of recommendations and prioritized them according to their importance for improving data quality and quality management. These recommendations were presented to EPA's Quality Subcommittee on March 8, 2001, and the Subcommittee has taken them under advisement. The list of recommendations appears below, followed by a description of each.

1. National Information Quality Management
2. Environmental Data and Metadata Standards
3. Performance Reporting
4. Data Transmission and Storage
5. Grants and Permits
6. Data Stewardship
7. Better Quality Assurance Project Plans

#1 - National Information Quality Management

EPA's current approach to Agency-wide quality assurance (QA) relies on decentralized implementation of broadly stated policies contained in EPA Order 5360.1, and the Agency Quality Manual. Theses documents describe the role of OEI's Quality Staff as providing quality assurance primarily for environmental data collection and technology development, and reviewing documents.

The Quality Staff develops policies and guidance and assesses their implementation across the Agency, but has little authority for assuring compliance in organizations that have not developed credible QA programs. The Quality Staff is not responsible for *coordination* of policy implementation across EPA on a day-to-day operational basis, nor is there a process for elevating and resolving common or shared issues to the Agency level.

Many examples illustrate the lack of a cohesive national quality system. For instance, the quality requirements in state grants programs are dramatically inconsistent. The Office of Air and Radiation has clearly defined quality assurance requirements for its air monitoring program, as does the Superfund program. But other EPA program offices do not and there are few incentives in place to compel a less inclined office, governed by quality-silent or weak statutes and regulations, to expend scarce resources to *assure* the quality its managers believe is already a part of their standard business process. The cost of inconsistent implementation among EPA's regional offices can be illustrated by a contractors' dilemma where their Quality Management Plan is approved by one region but disapproved in another resulting in confusion, frustration and additional costs.

After 20 years of using a decentralized approach to managing quality assurance at EPA, implementation of quality in the business processes for collecting, analyzing, using, and storing information is fragmented and inconsistent in program offices, regions, and laboratories; with little accountability for the results. This creates information quality vulnerabilities and results in inefficient data collection and analysis expenditures, barriers to information sharing, and the potential for lost credibility in Agency decisionmaking.

To improve EPA's quality culture and provide a national framework for achieving greater consistency in quality assurance policy implementation, the Workgroup has recommended that changes in the current quality management structure be effected.

1. **Create a National Information Quality Office**. This office would report to the Agency's chief information officer (CIO), supported by a network of regional and national program CIO's with explicit authority, responsibility and accountability to:

    - Assure consistent coordination and integration of quality across all EPA programs and regions by developing an Agency-wide EPA Quality Management Plan. The plan must describe how all sectors of the Agency Quality System work together to assure information quality. It must describe consistent roles, responsibilities, and processes for headquarters, national program offices, regional offices, delegated states, grantees, and contractors to implement quality procedures; and must establish core criteria to assure even implementation across the entire Agency.

    - Serve as the final arbiter for resolving differences in quality policy interpretation.
    - Implement and manage a formal data and information stewardship program that spans the entire data lifecycle.
    - Serve as a central Agency focal point for external contacts on quality policies and interpretation.
    - Lead an Information Quality Office initiative to influence the Agency's quality culture in positive ways, including:
        - ✓ Institute an education and training program among QA staff and managers to engender a *customer-assistance* orientation to quality assurance processes.
        - ✓ Offer broad Agency training to emphasize the role and value-added of quality assurance to all our work.
        - ✓ Shift the approach to QA to become more *results-oriented*, e.g., demonstrate the connection between Quality Management Plans and data quality.
        - ✓ Perform a sort of triage to identify national QA priorities that will inform managers where to target limited resources.

B. **Quality Assurance Manager Independence**. The Science Advisory Board found that the reporting status within EPA lowers the quality profile and denies quality assurance managers access to the proper level of authority, within program offices, regions. According to ISO Guide 25,[6] "The quality manager shall have direct access to the highest level of management." And,

[6] International Standards Organization, *General Requirements for the Competence of Calibration and Testing Laboratories.*

> "The quality assurance unit shall be entirely separate and *independent* from the personnel engaged in the direction and conduct of the study."[7] (Italics added)

Providing sufficient organizational independence for Agency quality assurance manager (QAM) positions assures that quality vulnerabilities will be raised to the proper level of authority. The QAM position must have sufficient level of placement, with access to senior management, grantees, and contractors, to be heard. Currently, there are QAMs in offices with substantial data collection responsibility that are not full-time positions, nor do they have sufficient access to their office management. To provide sufficient independence for quality assurance managers:

a. Require institutional placement of QA manager to ensure access to senior managers, and that they must hold a GS-13 level or above.
b. Guarantee an appropriate measure of independence to QA managers to avoid conflicts of interest.

#2 - Data and Metadata Standards

Metadata are defined here as the *who, when, why, what , where, and how*, of data values. Where metadata are absent, EPA is unable to "defend" its data, making the Agency vulnerable in terms of external inquiries, and because the public assumes data on our Web site are Agency "approved." To collect data that can be defended on their merits and gain a higher return on the enormous investments made in data and data systems by planning for the secondary use of data, quality assurance considerations need to be explicitly incorporated into OEI's data standards development process.

In OEI's first eighteen months, the standards process accounts for the successful completion of the six *Reinventing Environmental Information* data standards. Fourteen of EPA's major data systems are in various stages of implementing those standards on the back end–at the database level. To meet the large demand for approved data standards the current development process needs to be accelerated, and it also needs to be broadened to include scientific measurement data.

There are many drivers for requiring the collecting, documenting, and storing certain metadata parameters. Among them, the data quality language was inserted into the FY 2001 appropriations bills,[8] raising the possibility of a lawsuit where "inaccurate" public data are discovered. A lack of standard data definitions and metadata can also result in confusion and skewed analysis when incompatible data is wrongly compared. Data collection is a huge Agency investment (direct collections, grants to states and researchers). When data are treated as a reusable resource–for use after the initial collection

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[7] See 21 CFR 58; 40 CFR Part 160.35)

[8] Section 515, Consolidated Spending Bill H.R. 4577, Untitled Section of the Fiscal Year 2001 Consolidated Appropriations Act (P.L.106-554).

purpose–the return on the investment will be far greater. Where metadata are missing, data are of unknown quality resulting in decisions that may be unsound and indefensible. Non-standard data formats and missing metadata are both barriers to large-scale, regional and national analysis and comparisons. EPA's Quality System *requires* that where pre-existing data are used to make environmental decisions or new data collections are planned, the quality of the data *must be known and documented*.[9]

The following recommendations address the Agency's need for standardized metadata and data quality indicators.

A. Analyze EPA's commonly used scientific data types to identify where the most compelling needs for data standards exist. The selection criterion could be EPA's largest scientific data collections, or some other. Standardizing Superfund program data has been an identified need for years.

B. A series of Standards Action Teams should be convened to, 1) identify the needed elements for *core sets* of metadata (*who, what , how, when, where, why*), and 2) data quality indicators (*precision, bias, confidence level*). Standard transmission and storage formats for these elements can be developed using OEI's data standards process. The core set should consist of a minimum number of priority data elements and quality indicators.

C. Collection and documentation of core metadata elements will be required: 1) of all major EPA data collections, and these standard data fields will be required of when a data systems is developed or re-engineered. When data are collected, transmitted or stored, the inclusion of, or linkage to, any existing metadata connected to that dataset, will be required.

D. Linking technologies and data transmission languages such as XML should be identified for use in legacy systems that do not accommodate metadata storage, so that available metadata can be accessed with the corresponding data.

E. The workgroup should consider two options: 1) develop a series of core sets of metadata, specific to different data types, or 2) identify one core metadata set comprised of elements common to most data types, then require program offices to develop their own office-specific metadata requirements as a complement the core set.

F. A plain English educational brochure needs to be developed for non-scientific EPA staff, decision makers, and the public, to explain the role and importance of metadata to understanding issues such as random error, confidence and uncertainty. The brochure should be published and distributed, and a link displayed on EPA's Web sites wherever data are displayed to promote a more informed understanding and use of EPA's data.

G. Use OEI's data standards implementation process to incorporate standardized data formats and metadata requirements into all appropriate, data-related, Agency regulations, policies, permits, data system requirements, and Information Collection Requests.

#3 - Performance Reporting

A. **Data Assessments:** Perform standard data quality assessments of all major data bases every two years. A standardized protocol and criteria should be developed for performing data quality

[9] EPA Order 5360.1, Section 2.5.1.

assessments, using statistically significant sampling. The first assessment will create a baseline from which to judge all future progress. From this, the program can establish data system-specific improvement goals.

B. **Improve the FMFIA Reporting Process:** Reporting under the *Federal Managers Financial Integrity Act* (FMFIA) can promote greater accountability in improving the consistency of Agency data. A formal collaboration process should be developed between OEI and the Office of the Chief Financial Officer (OCFO) to identify national programs and regions that are not adequately addressing data quality management in their FMFIA reports, and reminders and assistance can be provided.

C. **Integrate Data Quality Management into the Government Performance and Results Act (GPRA) Processes:** To engender a responsive quality culture in EPA, a system of carrots and sticks should be employed. Tying program and regional development and *implementation* of Quality Management Systems to the Agency's *Planning, Budgeting, Analysis and Accountability* system and GPRA implementation efforts could provide the incentives. Since the GPRA process helps determine EPA's resource use, directly tying quality performance to this process would help improve and broaden the "quality culture" at the Agency.

#4 - Data Transmission and Storage

A. EPA should formally acknowledge that information technology systems and security provisions have a direct effect on the overall quality of our information, and should be explicitly considered part of the enterprise quality system. The Agency needs to develop explicit quality policies and guidance across the three functional areas of information, technology, and security.

B. Life cycle documentation should be required for all software as should the independent verification and validation procedures of the software system. Custom hardware should be subjected to comparable documentation procedures.

C. Explore the development of an Agency-wide metadata repository. This would achieve significant economies since individual systems would not have to store metadata information but could link to the appropriate metadata instead.

D. Provide guidance for systems managers, describing methods for checking the quality of transmitted data and making corrections. These steps must be included in system operational procedures, and be available to the project manager.

E. Conduct periodic quality review of systems as part of quality program reviews. Upgrade Agency software engineering guidance and policies (e.g., IRM Directives 2100) to require quality documentation.

#5 - Data Steward Roles and Responsibilities

Develop a policy to codify the Data Stewardship Network in EPA's Integrated Error Correction Process. Formally identify data stewards with the responsibility to guard data integrity from cradle to grave, or from data collection to data repository. The Data Stewardship Network should include staff from program offices, regions, and states; individuals with a vested interest in overseeing the development and use of reliable data.

#6 - Quality Assurance Project Plan Improvements

A. Quality Assurance Project Plans (QAPP) are the first line of defense for reliable data quality. When effectively developed, they encompass the thought and planning that are vital to an effective data collection process. The Intergovernmental Data Quality Task Force and Region 1 are developing guidance to help staff prepare streamlined and meaningful QAPPs. Many QAPPs currently are comprised mainly of "boiler plate" that has little to do with project requirements.

B. Training in QAPP development is a continuous requirement. Management must be committed to providing essential training.

#7 - Grants and Permits

Permits - It is important the Agency improves quality assurance requirements for its permit programs, which currently offer minimal assurance. Two possible approaches are:

A. Have each permit program assess the quality of data reported to EPA by permittees to determine whether the data are adequate for their intended use. This assessment could drive the need for regulatory change. If data are adequate, no regulatory change is necessary. If the data are inadequate for a given program, the program would be required to develop a plan to upgrade the quality of the data (this might include regulatory changes or other changes);

B. Identify other tactical points where change could be made relatively quickly that would lead to overall quality improvements. For example, improved data quality screening tools to prevent inaccurate data from entering the system.

Grants - The EPA Quality System could be modified to specifically require grants that contain environmental data operations (EDO) to have Quality Management Plans in accordance with EPA guidance. In addition, 40 CFR §§30 and 31 could be modified so that the burden to determine if there is an EDO in a grant is made by the QA staff of the organization approving the grant. The language in 40 CFR §31.45 is outdated and inadequate to ensure that grants having environmental data operations will establish adequate quality systems. The section needs to be rewritten. The Agency Grants Management Manual needs to have a section that adequately reflects the modified language in 40 CFR §31.45, and holds grants management officials accountable for the QA component of the grant.

Where We Go From Here

On March 22, 2001, the Quality Subcommittee members will meet in a closed-door session to decide their response to the recommendations presented in this paper. Based on the Subcommittee's direction, a Data Quality Strategic Plan (DQSP) will be drafted. The current intention is to distribute the draft Plan for review at the end of April, and later to meet with state representatives to receive their feedback on a second draft Plan. The Workgroup and others with an investment in the Agency's Quality System and data, hope that the Subcommittee's deliberations will result strategic in shifts in the Agency's culture and approach to information quality management, but we also understand the daunting obstacle of cultural resistence in a large organization. In short order we will know if the time for this Plan has arrived.

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REMEDIAL PROCESS OPTIMIZATION

Maj. Jeff Cornell*, Lt. Col. Daniel Welch, and Dr. Javier Santillan

Nearly fifty percent of the Air Force contaminated sites have completed the investigation phase, and have entered the remedial design / remedial action (RD/RA) phase. The Air Force FY2005 annual monitoring costs are estimated at $ 200 million. The cost of RD/RA will be equal or greater than the investigation phase of the ERP. To reduce costs, RD/RA must be based on attainable cleanup goals following systematic planing and appropriate data quality objectives (DQOs). The majority of RA projects require compliance Remedial Action-Operation (RAO) monitoring of their active remedial systems. Sites where the remedial action is complete, and/or where ground-water contamination is still present require Long-Term-Monitoring (LTM). RAO/LTM is dictated by the Resource Conservation and Recovery Act (RCRA); Comprehensive Environmental Response, Compensation and Liability Act (CERCLA); and Underground Storage Tank (UST) programs and is a costly necessity at most military installations. Consequently, improving the efficiency of these RD/RA and associated monitoring programs through Remedial Process Optimization has the potential for substantial cost savings.

Optimization of remediation cleanup actions will accelerate cleanup and site closeout. Monitoring programs supported by adequate systematic planing, appropriately established decision rules, and well defined data quality objectives are easier to manage. These projects promote tracking of contaminant plume trends and update of conceptual site models. The Air Force developed the Remedial Process Optimization (RPO) Handbook for the purpose of maximizing the effectiveness of all processes that lead to site closeout. This Handbook was reviewed by an interagency workgroup (US EPA, USACE, USGS, and NFESC. Beta Test results of the RPO Handbook are presented and discussed.

USING FIELD DATA ANALYSIS FOR ENVIRONMENTAL DECISION MAKING AND SUBSEQUENT REMEDIATION AT TWO EXAMPLE SITES

Laura L. Splichal, CHMM and George DeLullo, CDM Federal Programs Corporation, Kansas City, Missouri; Denver, Colorado

One of the major challenges in remediating contaminated sites is having quick access to quality data on which to base remedial decisions as onsite work progresses. Case studies are presented at two Superfund sites where field screening and field analyses are used to provide these data. Emphasis is placed on the importance of high quality field data, as these data are the basis for remedial decisions prior to receipt of offsite laboratory confirmation. The decision-making processes for remediating contaminated soils and structures are presented in addition to project specifics including data quality objectives, field data collection procedures, quality assurance/quality control procedures, and comparisons of the field data with offsite laboratory results.

Introduction

At Sites A and B discussed in this paper, CDM Federal Programs Corporation (CDM Federal) designed and implemented site remediation programs that removed both radium-contaminated soils and radon gas, with all cleanup activities geared to meet community concerns. The cleanups were designed to be complete and effective using streamlined approaches to allow the projects to quickly progress through final site characterization, design, construction completion, and site restoration. The programs would not have been as successful without thorough and effective quality assurance protocols that were incorporated into the design and data collection activities. Both sites are currently in later phases of remediation. To date, radon gas has been reduced to acceptable levels inside residences, contaminated soil has been removed from a number of properties, and over 850 properties at the two sites have been fully restored.

Site A

Site A was discovered in 1979 when the state environmental agency initiated a program to identify and investigate locations of former radium processing facilities within the state. Site A consisted of a total of 210 acres of residential and public areas in three different townships that contained radiologically-contaminated soil originating from local radium processing operations. Radium research and the radium products industry were prevalent in the site area from the early 1900s until the late 1920s as medical, commercial, and military uses were found for this radioactive isotope. Radium was used to destroy cancerous tissue and was applied as self-illuminating paint to watch and instrument dials, gun sights, and survey equipment. Several companies involved in these radium research and production activities were located in the site area during that period. By the early 1930s, increasing awareness of the hazards of radium and the discovery of richer uranium ore in Africa caused the radium industry to disappear from this geographical area. However, the discarded materials and process waste from the industry were left behind. Locations in each study area where the contaminated material was deposited, and still existed at the beginning of site activities, were termed “core areas.” Radium-contaminated waste was apparently brought to these core areas and placed among ash and other waste materials. During subsequent residential development, channeling and diversion of surface drainage was necessary, and earth was moved during the construction of roads and houses. Contaminated material was, therefore, mixed with non-contaminated soil and fill throughout the site, with the highest levels of contamination present in the core areas.

Site A encompassed over 800 commercial and residential properties in addition to public streets and parks. Above-background levels of gamma radiation indicating soil contamination exceeding cleanup standards were identified at more than half of these properties. The remaining properties either appeared to be below the cleanup standards or did not have sufficient testing to be classified. This soil contamination caused elevated levels of indoor radon gas, as well as elevated indoor and outdoor gamma radiation throughout the study area.

Site A was subsequently listed on the National Priorities List (NPL) in 1985, and the U.S. Environmental Protection Agency (EPA) signed a Record of Decision (ROD) for the site in 1989. The ROD provided a final solution for some properties and interim solutions for others. It required total excavation of all contaminated material above cleanup standards from the most highly contaminated properties, with offsite disposal of the waste. The cleanup standards specified in the ROD were < 5 picoCuries/gram (pCi/g) for radium-226 in surface soil, and <15 pCi/g in subsurface soil. These extensively contaminated properties (e.g., Category I) posed the greatest threat to human health and would be difficult to remedy without excavation. The ROD provided for excavation of “hot spots” on other properties (e.g., Categories II and III) where the removal of small quantities of near-surface contaminated material would provide a final remedy and bring the properties into compliance with cleanup standards. The ROD also required interim actions at some properties, including the installation of engineering controls, to mitigate health risks associated with exposure to radon gas and gamma radiation prior to completion of the remedial actions. Additional investigations and monitoring were specified for a number of properties (e.g., Category IV) where radium-contaminated soil was present above soil cleanup standards, although health guidelines were not exceeded. This phased approach outlined in the ROD allowed EPA to begin excavating the radium-contaminated materials from the most highly contaminated properties, while mitigating the health impacts associated with exposure to radon gas and gamma radiation at other properties in a timely manner.

Objectives

Major goals of the Site A remedial design investigation included:

- Augment the current database for the Category I, II, and III properties so that the vertical and horizontal boundaries of the contamination are identified with reasonable accuracy where excavation is required;

- Collect data sufficient to perform the design of engineering controls for properties that will not be immediately excavated; and

- Review existing data and collect additional data, where required, to ensure that all of the properties are correctly categorized.

Quality Assurance Planning

A Quality Assurance Project Plan (QAPP) was prepared pertaining to the Site A remedial design/remedial action (RD/RA) construction support services and related environmental studies. It incorporated a graded quality assurance (QA) approach based on the relative importance of an item or activity on safety performance, reliability, and project objectives to ensure results were valid and in compliance with project criteria. Two of the specific objectives stated in the QAPP were a) to provide adequate confidence in the accuracy, reliability, and appropriateness of reported conclusions, recommendations, and associated studies, and b) to manage RA construction support service activities so that remedial designs were implemented accurately.

To achieve the project objectives stated in the QAPP, QA objectives were established for the Site A data collected during sampling efforts. These objectives focus on what's termed the PARCC parameters: precision, accuracy, representativeness, comparability, and completeness. At the time the QAPP for this project was prepared, the data quality objective (DQO) process required by EPA included establishing qualitative and quantitative goals for each of these parameters. The specific QA objectives are listed below:

- Ensure the accuracy of the collected data meets the specific goals for the analytical method used. The accuracy goal for all radiological analyses was 10% from the true value.

- Ensure the precision of the collected data meets the specific goals for the analytical method used. The precision goal for the analyses was 20% difference between individual duplicate values.

- Ensure completeness of the data based on the percentage of valid data obtained from field and offsite laboratory tests.

- Ensure the data are representative of the medium/environment sampled.

- Ensure the comparability of the data sets through the use of standardized sampling and measurement procedures and use of certified calibration standards for field instrumentation and equipment.

Readiness reviews were conducted prior to the start of each phase of field activities to ensure all preparatory tasks were complete and to formulate and communicate the action plan to commence the field activities. The readiness reviews incorporated all project management and field personnel and ensured field personnel had all required training and background information required to perform the work successfully.

Field audits were conducted in conjunction with the remedial design investigations and RA activities to ensure work was conducted in accordance with the Remedial Design Work Plan and QAPP. Field audits were conducted by QA personnel, independent from the personnel performing field activities. This independent assessment allowed an additional quality check to ensure field activities were performed in accordance with all applicable procedures.

Pre-Design Characterization Activities

CDM Federal conducted a detailed investigation of radiological and surveying data acquired from previous contractors and regulatory agencies prior to collecting any additional data. By compiling previous data acquired at the various site properties, CDM Federal personnel determined what additional information was required to determine if a property required remedial action. This background evaluation of previous data resulted in acquiring only the necessary amount of samples to determine whether to remediate a particular residential property. This evaluation also allowed only the necessary fieldwork to be conducted where data were not available. New data collected by CDM Federal, in addition to the previously existing background data, provided the basis for remedial design engineering at contaminated properties, and confirmation that properties not requiring remedial action were within appropriate guidelines.

The most highly contaminated properties were located almost exclusively inside three core areas where radium-contaminated soils were originally disposed. Additional data at these properties were primarily needed to verify the vertical contamination profile. Investigations at the remaining properties were conducted to identify "hot spot" contamination and determine whether immediate excavation or interim measure engineering controls would be implemented. Pre-design investigation activities that were conducted at the Site A properties are listed in Table 1.

Field meters specified for use at Site A included a gamma scintillometer (2" x 2" NaI detector with scaler) to detect elevated gamma radiation from uranium-238, radium-226, thorium-232, an alpha scintillation probe to detect elevated alpha radiation from thorium-230, and a beta-gamma pancake-geometry Geiger-Mueller probe to detect beta and gamma radiation. All onsite equipment was calibrated daily in accordance with manufacturer's instructions. If equipment was found to be out of calibration, any data that was collected with the non-compliant equipment was flagged and re-collected if possible. Malfunctioning equipment was immediately replaced with backup equipment that was operating properly.

During pre-design investigation activities, CDM Federal rapidly analyzed samples onsite using a Canberra "Genie 2000" multi-channel analyzer (MCA) with gamma scintillation detector. This instrument is termed the "Quick Count" system. Early in the program, samples were field analyzed for radium-226, and later for radium-226 and thorium-232, the target analytes for the site. System background and calibration checks were performed daily using two different radium-226 standards prior to sample analysis. As a QA measure, five percent (5%) duplicate counts were conducted to demonstrate that the system remained within required quality control (QC) limits.

Table 1. Site A Pre-Design Investigation Activities and QC Requirements

INVESTIGATION ACTIVITY	REQUIRED QC*
Outdoor walkover gamma surveys – performed to identify boundaries of soil contamination. Surface soil samples were collected using a 10' x 10' grid across the identified contamination area. Sampling was focused at areas where survey gamma readings were greater than 20,000 cpm. Soil samples were analyzed onsite using the Quick Count system, and results were confirmed by offsite laboratory analysis.	10% duplicates for all measurements and soil samples
Subsurface investigations – performed at areas with high surface gamma readings to identify the vertical extent of contamination. This was performed by hand augering 5-foot soil borings and taking downhole gamma readings at 6-inch intervals within each boring. Subsurface soil samples were collected from intervals with downhole gamma readings greater than 30,000 cpm. Soil samples were analyzed onsite using the Quick Count system, and results were confirmed by offsite laboratory analysis.	10% duplicates for all measurements and soil samples, minimum of one duplicate per boring
Indoor walkover gamma surveys – performed inside basements using a gamma scintillometer, i.e. 2" x 2" NaI (sodium iodide) detector with scaler.	10% duplicates for all readings
Radon measurements – measured inside basements using alpha track detectors (ATDs) to determine the necessity for and appropriate type of engineering controls if radon levels exceeded the 4.0 picoCuries/liter (pCi/L) criteria specified in the ROD.	10% duplicates for all readings
Building surface surveys - conducted to identify alpha and beta-gamma surface contamination of structures.	10% duplicates for all readings
Gamma exposure rate measurements - performed both outdoors and in basements to determine if any portion of the property exceeded the health guidelines established for gamma exposure (20 microRoentgen/hour [:R/hr]).	10% duplicates for all readings

*All field measurements and offsite laboratory samples were duplicated at a 10% frequency. Precision requirements were +/- 20%.

Figures 1 and 2 present graphs correlating offsite laboratory results with the field Quick Count results, respectively, for radium-226 and thorium-232 analysis of subsurface soil samples collected from several properties at the pre-design investigation stage. The figures indicate the correlation between the Quick Count results and offsite laboratory results for the two radionuclides. For radium-226 (Figure 1), a Quick Count result of 4.3 pCi/g related to an offsite laboratory result of 5.0 pCi/g. For thorium-232 (Figure 2), a Quick Count result of 5.5 pCi/g related to an offsite laboratory result of 5.0 pCi/g. This correlation was important to determine the Quick Count results that would indicate whether a property required remedial action.

RD/RA Activities

CDM Federal prepared remedial designs for the properties requiring remedial action based on the pre-design and historical data. A remedial action contractor performed the RA activities at the various Site A properties. Remedial actions included excavation of the contaminated soils from around and below houses, even under the foundations. Several alternatives were available for removal of contaminated materials against or beneath house foundations. Material against a foundation or basement wall was removed by reinforcing the wall as necessary, excavating, and cleaning the wall by brushing and washing. Contaminated material extending a short distance under foundations was removed by incremental excavation and backfilling and compaction to avoid weakening the structure. More extensive contamination was removed by supporting the structure then underpinning or tunneling beneath the residence, by relocating the home, or in extreme cases, by acquiring the property and demolishing the house.

During soil excavations, the RA contractor performed walkover gamma scans and soil sampling with onsite gamma Quick Count analysis. If gamma scans indicated soil contamination above 30,000 cpm, then excavations were continued in that area. After all gamma scans indicated acceptable levels, soil samples were collected for onsite analysis to ensure all portions of the excavation met the cleanup criteria. A challenge specific to Site A included ash content in the soil that created false positives in the gamma readings. The field analyst considered any interferences due to ash content in the soil, and professional judgment was used to determine if positive results in the sample may be due to ash, rather than radionuclide content. All surface and subsurface Quick Count and gamma screening data collected during excavation activities were logged into a pen-based computer for accurate data storage, recall, and tracking.

After excavations and other remedial actions were finished, the RA contractor verified the remedial action was complete by performing final field measurements and offsite soil sampling confirmation.

Independent Verification

CDM Federal provided independent verification of the effectiveness of the remedial actions after the RA contractor was finished to verify that the remedial actions were accomplished in accordance with the standards and criteria established for the project. Independent verification measurements consisted of soil sampling from excavated areas, gamma exposure measurements for both indoor and outdoor remediated areas, working level radon/radon decay product measurements from inside remediated structures, and contact alpha and beta-gamma readings from decontaminated surfaces. The Verification Protocol, itself, was a QA measure that was used to ensure remedial actions achieved the cleanup criteria at each property. Its implementation allowed rapid correction if it was determined that additional excavation was required, or engineering controls were not completely effective. Each post-RA measurement activity is described below.

Soil Sampling Procedures

Walkover gamma scans were conducted across the entire site, with one-minute concentrated readings at selected anomalous areas to ensure there were no areas with elevated activity. Composite soil samples were then collected from each 10m x 10m grid (900 ft^2) area. Sampling grids were established such that samples were collected from the non-disturbed edges as well as from the bottom of the excavation. Ten percent were duplicate samples for duplicate gamma analysis in addition to alpha analysis.

Soil samples collected during post-RA soil sampling were analyzed onsite for radium-226 and thorium-232 using the Quick Count system to verify that an excavation had been completed and to specify the samples with elevated radioactivity for offsite laboratory confirmation analysis. Quick Count analysis was more challenging during the verification stage as compared to the pre-design stage because gamma activity was much lower, near the cleanup criteria of 5 pCi/g, so less measurement error could be tolerated. Quick Count data were evaluated using a revised RD criteria established by EPA of 7 pCi/g for combined radium-226 and thorium-232, or 5 pCi/g criteria for these analytes individually.

To maximize the accuracy of the data, soil samples were dried for a 12-24 hour period prior to analysis to allow the radionuclides to uniformly distribute throughout the sample matrix and to eliminate the water in the sample that shields detection of the radionuclides and makes the sample heavier, effectively diluting the results. These factors cause “wet” samples to have lower results than “dry” samples which can lead to a determination that a property has been remediated, when in fact, the clean up criteria has not been achieved. For quick count data obtained from wet sample analysis, measurement error was considered to be "50-100% due to sample moisture. Error for dried sample measurements was considered to be "10%.

As a QA measure, five percent (5%) duplicate counts were conducted to demonstrate that the system remained within required control limits, and daily calibration procedures were followed to ensure the accuracy of the instrument. The precision criterion of "20% difference between the results was often difficult to achieve due to inherent heterogeneity of the samples. One small particle of ore in one of the samples could create a large difference between sample results. If the precision criterion was exceeded, the duplicate samples were re-counted and the results were documented. Based on the re-count results, field decisions were made as to whether results were acceptable, the samples should be re-collected, or additional excavation was required.

Gamma Exposure Measurements

Gamma exposure measurements were also conducted to ensure there was no elevated exposure to residents. These measurements were taken using a pressurized ionization chamber or an equivalent instrument. At least five measurements were taken per each 10 square meter area remediated outdoors. Alternatively, five measurements were taken in each room where engineering controls were implemented to reduce indoor exposure rates. At very few properties were the readings above 20 :R/hr; the scans were performed as additional safety checks to ensure all gamma exposures were below the health criteria.

Surface Activity Measurements

The effectiveness of the RA performed to reduce either the alpha or beta-gamma activity on surfaces (i.e., floors and walls) was determined with direct contact field instruments for final activity, and swipes to measure removable activity. The remediated surfaces were divided using a 1m x 1m grid system. Five measurements for fixed activity were collected from each grid. One measurement was taken at each grid intersection, and one from the center of each grid square. In addition, one cloth or paper swipe was collected from each grid square.

Alpha measurements for fixed contamination were taken using an alpha scintillation probe and appropriate scaler. The fixed beta-gamma measurements were collected using a pancake-geometry Geiger-Muller probe.

Radon Measurements

The ultimate effectiveness of the remedial actions was determined by collecting a grab air sample from each room that contained elevated radon concentrations, and the use of passive radon monitors for one year after the RA was implemented. Duplicate measurements were collected by placing 4 ATDs at each measurement location. One ATD was submitted for analysis at 2 months, the second at 4 months, and the final 2 ATDs at one year. If differences greater than 20% were obtained, a recount by the laboratory was requested. If the radon level after one year was determined to be above 4 pCi/L, additional investigations were performed at the property to identify any missed areas of contamination. After the radon measurements were complete and below 4 pCi/L, the ATDs were relinquished to the property owners, if they wished, for them to continue radon monitoring in their homes.

Notification and Final Property Documentation

Following the post-RA measurements and field sample analyses, excavations were determined to be complete, and the excavations were backfilled. These decisions were based on field data and could have had costly implications if the data were inaccurate. Split samples were collected for offsite analysis during the independent verification process, and the properties were not finally certified as clean until results from the offsite laboratory were received.

Following successful independent verification and completion of site restoration, the property owner(s) were notified that work on their property had been completed, and a property completion report was prepared and submitted. It should be noted that, to date, none of the properties at Site A have had to be reworked due to offsite analytical results differing from the field results. A few properties required re-work due to continued radon levels above 4 pCi/L that generally indicated a pocket of contamination had been missed. In these cases, the property was re-investigated to identify the source of the high radon levels.

Site A has been expanded to include other properties in addition to those specified by the ROD. Currently, 700 of the over 800 properties have been investigated and/or remediated. As mentioned earlier, none of the properties required re-work due to offsite sample results differing from the field results, which is a good indicator of effective QA/QC field practices.

Site B

Site B is located in an urban area near Site A that consists of commercial, light industrial, and residential properties. The original facility location, which initiated operations in 1917, consisted of refining radium from carnotite ore. As many as two tons of the ore were processed per day at the facility, with each ton yielding only 5 to 7 milligrams of radium. After refining, the processed waste ore was temporarily stored at an inactive part of the facility and later disposed offsite. Most of the homes in the surrounding residential area were constructed prior to facility operations. It is likely that the processed wastes were used as backfill material for structures added after the homes were built or for landscaping purposes at these properties. These activities occurred in various stages over a period of years from when the facility ceased operations in 1926, until the 1970s when the EPA starting conducting investigations in the area due to alleged illnesses afflicting former facility employees. Contamination at Site B is generally located at more shallow depths than at Site A because most houses at the site had already been constructed before facility operations began.

The responsible state regulatory agency was informed by the EPA that the residential properties near the facility were a potential hazardous waste site. Findings from subsequent investigations led to the inclusion of Site B on the NPL in late 1983.

Subsequent gamma radiation monitoring at the properties associated with Site B indicated extensive areas of elevated gamma readings, similar to Site A. In 1995, the EPA directed CDM Federal to conduct a Radiological Field Investigation at Site B. Results from the gamma exposure rate surveys and radon surveys at the former facility's buildings were consistent with results obtained during previous investigations performed by the state regulatory agency. Further building scans of adjacent buildings and residential properties also detected elevated radiological contamination.

Overall, the EPA identified several properties that potentially exhibited radiological contamination due to their close proximity to the former facility. The residential properties identified as having greater than the 8.5 :R/hr isopleth during an aerial gamma overflight of the neighborhood encompassed an area of nine city blocks. After some initial investigation, the EPA decided to expedite the remedy selection process at several residential properties rather than to continue lengthy field investigations. The three potential remedial alternatives identified for the residential properties included: 1) No Additional Action; 2) Engineering and Institutional Controls; and 3) Excavation with Offsite Disposal. After further review and comment, the EPA signed the ROD for Site B identifying excavation and offsite disposal as the preferred remedial alternative.

Objectives

- Major goals of the Site B pre-design investigation included the following:

- Use design economy, where possible, for both the data collection/engineering and remedial action stages for all impacted properties.

- Conduct pre-design investigations to define, within the limits of known data, the actual lateral and vertical limits of soil contamination and extent of building material contamination.

- Define the areas of contamination existing beneath structures by performing subsurface investigations to determine the need for contaminated soil removal; define what property features would be impacted by remedial action; and estimate the quantity of contaminated soil and building materials to be removed.

Quality Assurance Planning

For Site B, the DQOs included qualitative and quantitative goals and limits. These goals and limits were established for field and laboratory data and provided the means by which data reviewers could assess whether the goals of the project were met. The qualitative objectives provided descriptions on how the data would be used to support decisions for conducting restoration of the residential properties at Site B. These qualitative objectives were:

- Confirm the radiological data collected during previous investigations;
- Collect supplemental data to fill in gaps from previous investigation findings; and
- Identify the hazardous or potentially hazardous conditions that could affect the public, personnel, or the environment during performance of remedial action.

Quantitative DQOs establish numeric limits for acceptable results received from the subcontracted offsite laboratory. The numeric limits aid in establishing a level of confidence and degree of usefulness for the data collected as part of the field investigation. The numeric limits are tied directly to the intended end use of the data and include analytical detection limits, precision, accuracy, quality control frequency, and completeness.

The decision-making process on whether to remediate Site B residential structures or dispose of contaminated soil on the properties depended on both the qualitative and quantitative objectives discussed previously. The qualitative objectives were met by evaluating previous investigation data obtained from each residential property and performing a pre-design field investigation using the necessary onsite radiological equipment. Previous investigations revealed that radium-226 was a valid primary indicator of overall soil contamination that included major gamma emitters, isotopic thorium, and isotopic uranium in addition to radium-226, so this was the target isotope that was measured by field instruments. Radiological equipment was required to meet the cleanup criteria limits established by Site B's ROD for contaminated soil and building material, with radium-226 not to exceed 5 pCi/g. In addition to soil contamination at Site B properties, indoor radon levels in residential property structures were also determined. The action level for radon-222 in indoor air was established by the ROD at 4 pCi/L.

Pre-Design Investigation Process

Before mobilization at Site B, natural background surface gamma radiation measurements in the general Site B area were evaluated from previous investigations, and an estimated mean was determined. In addition, indoor natural gamma background data were generated to reflect the influence, or lack of, from building materials that constituted the residential structures. Finally, background radon decay product concentrations were determined as a function of local soils and building material types. Background values used for the Site B residential properties were obtained by using the state regulatory average for the township/county. These particular activities were conducted to ensure that no external bias was inadvertently added when quantitative data were obtained for the residential properties.

Prior to the pre-design investigation, CDM Federal personnel conducted a detailed evaluation of existing data for the site properties and determined what additional information was required to support preparation of remedial action and remedial designs for these properties, if required. This was a similar process as was used for Site A that allowed only the minimum amount of samples to be collected in areas where data were not available.

Pre-design field activities included indoor and outdoor surface walkover gamma scans, radiological and geological subsurface investigations, subsurface soil sampling and subsequent offsite laboratory analysis, determination of indoor radon levels, indoor alpha scans, and building material sampling and analysis. Frequent QC checks on the raw field data were conducted to determine with confidence the best option for remediating residential properties prior to receiving confirmation analysis results from the offsite laboratory.

Equipment Calibration and Maintenance

During the mobilization phase at Site B, radiation detection and measurement equipment were frequently calibrated and field-tested. Daily background and source checks on all equipment were performed to ensure all data obtained were reliable, accurate, precise, and useable within the required criteria stated in the Site B's QAPP, referred to as a radiological data acquisition plan (RDAP). Detailed and extensive calibration records were kept in designated logbooks or on separate calibration forms.

As an additional quality control measure, field personnel would evaluate calibration data at the end of each week to determine any possible trend indicating equipment bias. If there was an obvious trend of low or high bias with calibrating any piece of equipment, including possible radiological contamination that increased the background level of the detector, it was removed from operation and serviced. Usually an additional cleaning or calibration maintenance according to manufacturer's specifications was sufficient to ensure proper operation of the field equipment.

Field Screening Correlation

To identify the Site B properties requiring excavation, CDM Federal personnel developed correlations to determine the surface and downhole gamma instrument reading levels corresponding to 5 pCi/g radium-

226 in soil, as determined by the laboratory analysis. This correlation analysis enabled CDM Federal to expedite the pre-design process and keep the number of samples requiring laboratory confirmation analysis to a minimum.

For surface soil readings, a cutoff of 13,000 cpm was used to delineate surface contamination potentially above 5 pCi/g of radium-226. Soil borings were performed in these areas to obtain subsurface soil data. A cutoff level of 20,000 cpm was used to identify potential subsurface contamination above 5 pCi/g of radium-226 using downhole gamma counting activities. It should be noted that these levels are lower than those used at Site A, as background concentrations and interferences were lower for Site B than for Site A.

With the cutoff criteria established for surface and subsurface soil contamination, field personnel conducted the various pre-design investigation activities to determine whether remediation of a residential property was required.

Residential Property Investigations

Table 2 indicates the major pre-design activities and associated quality control requirements that were conducted during the Site B residential properties investigation. The detailed data acquisition process for the outdoor surface gamma surveys, downhole gamma logging, and confirmation soil sampling is discussed below.

Outdoor Surface Gamma Survey

Outdoor surface gamma surveys were performed to confirm the outdoor areas of elevated gamma radioactivity at the surface and define/redefine activity boundaries previously identified. Measurements for this activity were made with a Ludlum 44-10 2" X 2" sodium iodide (NaI) crystal gamma scintillation detector coupled with a Ludlum 2221 scaler/ratemeter.

Field personnel performed a layout of a 10-feet square (10 ft^2) grid at each property to locate outdoor areas of elevated gamma activity within the property's boundaries. At areas with elevated gamma radiation, additional meter readings between grid points were taken to define the extent of radiological contamination. A duplicate measurement was made with the meter at least every ten readings. A duplicate reading was required to be within 10% of the original reading. All information was recorded in a pen-based laptop field computer. The information was then downloaded at the end of the shift and reviewed by the field team leader prior to being entered into the overall Site B database. As a result, the information was quickly assimilated, and maps were generated to indicate potential "hot spots" around each residential property.

Table 2. Site B Pre-Design Investigation Activities and QC Requirements

INVESTIGATION ACTIVITY	PARAMETER [Criteria]	REQUIRED QC*
Outdoor Surface Gamma Survey	Gamma Activity [13,000 cpm]	10% duplicates for all readings
Downhole Gamma Logging	Gamma Activity [20,000 cpm]	10% duplicates of readings, or one duplicate per borehole at a minimum
Confirmation Soil Sampling with Offsite Laboratory Analysis	Radium-226 [5 pCi/g]**	10% duplicates of samples collected
Indoor Surface Gamma Survey	Gamma Activity [13,000 cpm]	10% duplicates for all readings
Charcoal Canisters/ATDs	Radon-222 [4 pCi/L]**	10% duplicates for all readings; 5% blanks of canisters collected
Building Materials	Radium-226 [5 pCi/g]**	10% duplicates of all samples collected

* The precision requirement for all onsite and offsite field duplicates was " 20% difference.
**ROD cleanup criteria.

Downhole Gamma Logging

Downhole gamma logging was performed to support development of an accurate determination of the volume of contaminated soil requiring excavation. The depth of contaminated soil at the Site B properties was determined by lowering a Ludlum 44-10 2" X 2" NaI gamma scintillation detector coupled by a 10' cord to the Ludlum 2221 scaler/ratemeter which recorded gamma radiation counts per minute at measured six-inch intervals down a vertical hole. Depths generally ranged from 3-6 feet depending on possible contamination and where groundwater was encountered. The maximum depth for downhole gamma logging was 10 feet. A duplicate measurement was made with the meter at least once per borehole, or 10% of the readings, whichever was greater. A duplicate reading was required to be within 20% of the original reading. All information recorded was similar to the process conducted for the outdoor surface gamma survey using a pen-based computer.

Confirmation Soil Sampling

If any of the downhole gamma readings exceeded 20,000 cpm, a soil sample was collected from the 0.5-foot interval with the highest gamma readings for offsite gamma spectroscopy analysis in a subcontracted laboratory to verify that soil activity was above the radium-226 ROD cleanup criteria (5 pCi/g), thus requiring remedial action. At least 10% of submitted samples were duplicates to assess the laboratory’s precision. Ten percent (10%) of the samples were additionally submitted for alpha analysis.

Additional activities with similar QC processes as described for the outdoor surface gamma survey, downhole gamma logging, and subsequent confirmation soil sampling and analysis included placing of charcoal canisters or ATDs which measured the radon-222 concentrations in air within residential structures, surface alpha surveys which measured any elevated alpha readings on residential surfaces, radiological scanning of home contents, and indoor surface gamma surveys which, similar to outdoor, measured elevated gamma activity in residential garages, basements, walls, and floors using a 5' x 5'grid.

All of the pre-design field data acquired at the Site B residential properties were assimilated and promptly summarized for the client. This information provided sufficient data to support remedial action decisions including determination of the volume of contaminated soil requiring remediation, initiation of the remedial design process if residential structures were impacted, or the determination that no further action was required (residential property considered clean). After the field data were provided to CDM Federal's client and RD/RA activities had been initiated as appropriate, offsite laboratory analytical results were received and adjustments to the remedial action decisions, if any, were made. However, due to the thorough historical/background data search/review and precise quality-conscious pre-design information that was submitted based on field data, minor or no changes were usually required.

Post-Remediation Verification

A remedial action contractor performed the excavations and other remedial actions at each property, then performed post-RA sampling to determine the properties had been remediated.
Similar to Site A, CDM Federal performed post-remediation verification activities after the RA contractor was finished, as an independent QC verification check, to ensure each residential property met the cleanup criteria. Gamma radiation scanning and verification soil sampling was performed to determine the extent of any required secondary excavation. Remediated areas found to exceed one and a half times the background count rate were marked for follow-up measurements. As in the pre-design investigation, field screening using gamma spectroscopic equipment was used, except a smaller 5' x 5' grid was used during the verification process.

After field radiological screening measurements indicated gamma activity less than 20,000 cpm across the entire remediated area, one composite soil sample was collected from each 900 square foot area (at a minimum) for offsite laboratory analysis of radium-226. If the offsite data indicated radium levels were less than 5 pCi/g, and indoor radon gas levels remained less than 4 pCi/L, remediation at the property was considered complete. As with the pre-design investigations, duplicate samples were collected at a 10% frequency for both the onsite field readings and offsite laboratory samples to check field and laboratory precision. To date, remedial actions have been completed at 166 Site B properties, with a still-expanding investigation area beyond that indicated in the ROD. The total extent of contamination at Site B is, at present, still undefined.

Conclusion

At Sites A and B, QC measures implemented in the field allowed the projects to progress rapidly based on field data rather than having to rely on offsite data that takes longer to obtain. The various QC measures including multiple counts and verification procedures ensured the data were correct, within a reasonable confidence level, which allowed the field data to be used to make remedial decisions at the various properties that were impacted at each site.

Although contaminant sources for Sites A and B and resulting site contamination were similar in nature, the QA/QC processes were somewhat different for each site. Also, several circumstances were different in that contaminated soil was found at deeper depths and beneath public streets and parks at Site A, which presented different challenges from Site B, where contaminated soils were shallower and confined to private properties. Remediation processes, at both sites, however, relied heavily on the accuracy of field data to keep the projects progressing as quickly as possible.

For residential properties with elevated gamma and alpha activity, each particular phase of the investigative/remediation process required approximately one year to complete. Without the detailed background data evaluation, pre-design investigation, and quality control to expedite the process, the remediation process would have taken several years. Conducting a detailed, informative pre-design investigation with definitive quality control requirements and having a smooth, quick transition from site characterization investigations to remedial action, not only saved time and funding in remediation costs for the government, but also helped minimized the uncertainty for the residents involved.

The neighborhoods at Sites A and B, once threatened with life-threatening radioactive contamination and continually decreasing property values, now boast remediated tree-lined parks, remediated yards, and new streets. Community confidence in the government process has been increased, and residents once again are able to enjoy their restored neighborhoods.

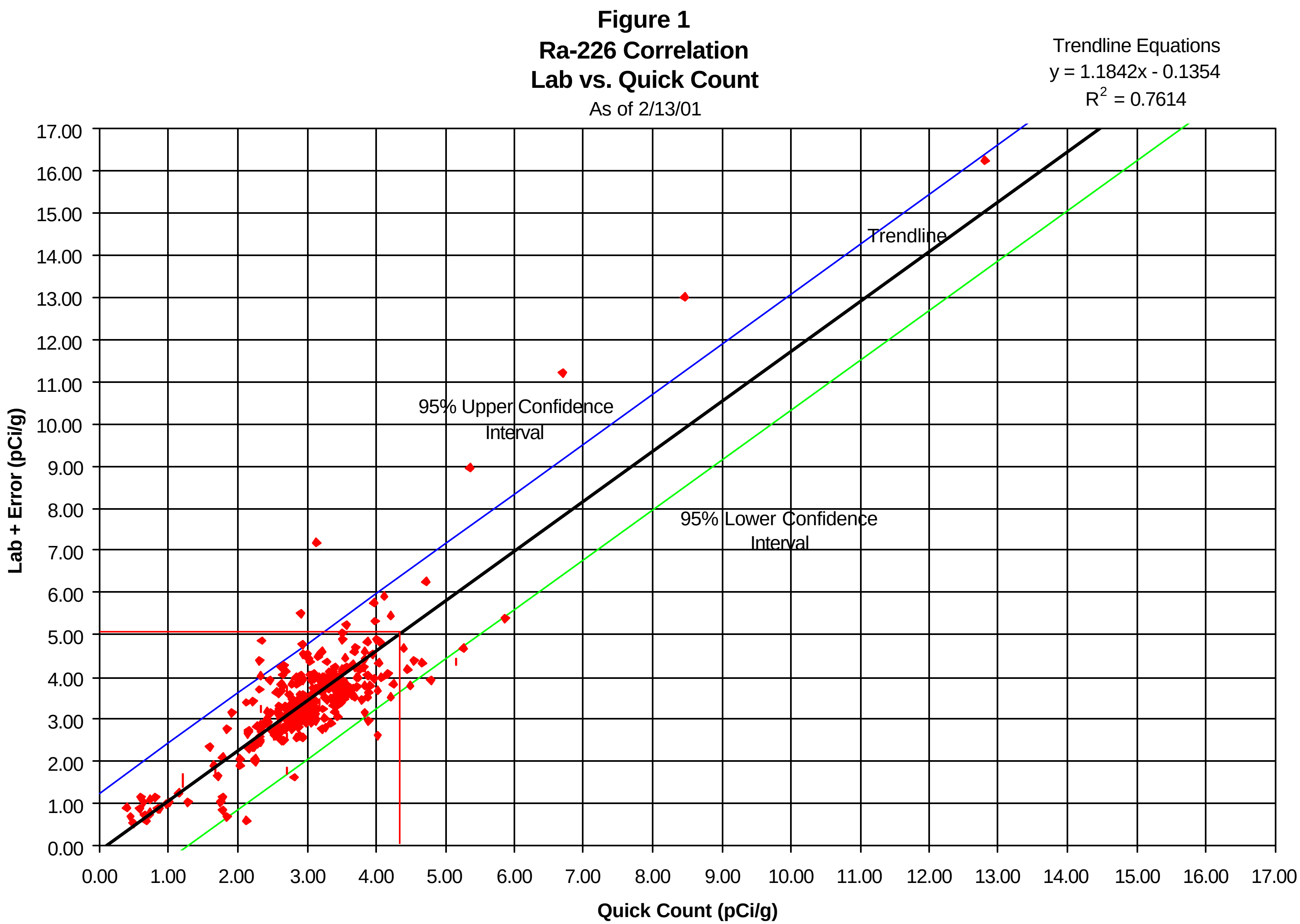
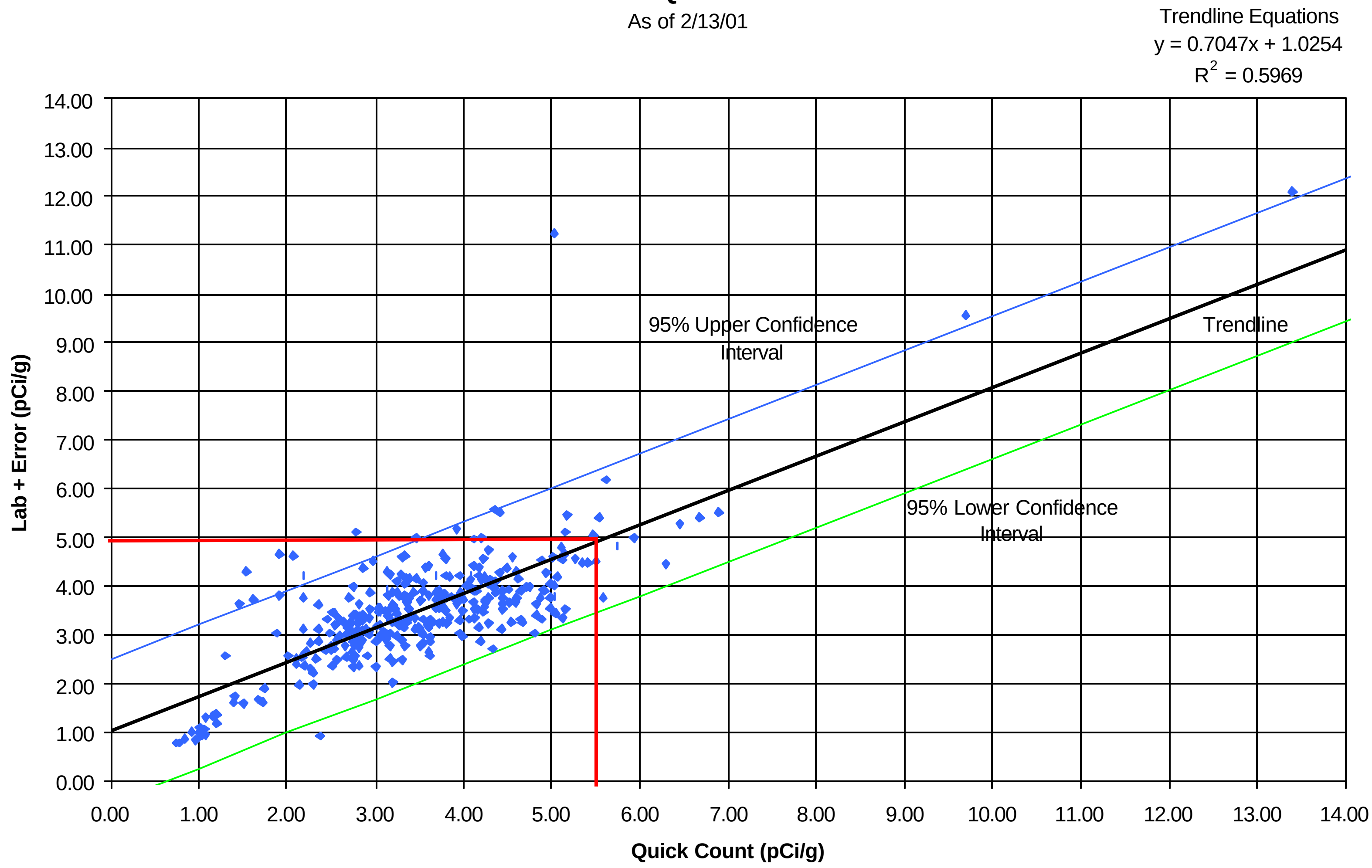


Figure 1
Ra-226 Correlation
Lab vs. Quick Count
As of 2/13/01
Trendline Equations
y = 1.1842x - 0.1354
R2 = 0.7614
Trendline
95% Upper Confidence Interval
95% Lower Confidence Interval
Lab + Error (pCi/g)
Quick Count (pCi/g)
0.00
1.00
2.00
3.00
4.00
5.00
6.00
7.00
8.00
9.00
10.00
11.00
12.00
13.00
14.00
15.00
16.00
17.00

Figure 2
Th-232 Correlation
Lab vs. Quick Count
As of 2/13/01



FY2000 HIGHLIGHTS OF QA ACTIVITIES WITHIN ORD'S LARGEST MEGALAB—NHEERL

Brenda T. Culpepper, U.S. EPA

The EPA Office of Research and Development's National Health and Environmental Effects Research Laboratory (NHEERL) has more than 700 staff members in 6 states. NHEERL conducts research on the effects of contaminants and environmental stressors on human health and ecosystem integrity. NHEERL's research mission and goals help the Agency to identify and understand the processes that effect our health and environment, and help the Agency to evaluate the risks that pollution poses to humans and ecosystems. The soundness, effectiveness, and credibility of EPA's regulations ultimately rest on the scientific and technical bases for these actions. A sound QA program can help ensure data quality. During FY2000, NHEERL quality professionals performed 32 in-depth project audits within the laboratory's 9 research divisions. Additionally, more than 800 performance evaluations, 20 surveillances of studies in progress, and 6 data quality assessments were performed. More than a million dollars was invested in QA/QC activities such as instrument calibrations, equipment maintenance, and travel dollars to conduct audits, etc. Another $44K was invested in QA training of 330 staff members. Additionally, NHEERL was recognized in an ORD "Best Practices Identified in Management Review" for developing and presenting a 90-minute course entitled "Guidelines for Laboratory Recordkeeping." Copies of the guideline document and the course in PowerPoint can be found at the NHEERL QA URL Address:

http://www.nheerl.epa.gov/policy_guidance/qa/index.htm

ISO 19011:2002 - A COMBINED AUDITING STANDARD FOR QUALITY AND ENVIRONMENTAL MANAGEMENT SYSTEMS

Gary L. Johnson, U.S. EPA, Office of Environmental Information

Abstract — In a precedent-setting decision in 1998, the International Organization for Standardization (ISO) directed ISO Technical Committee (TC) 176 on Quality Management and ISO TC 207 on Environmental Management to develop jointly a single guideline standard for auditing quality and environmental management systems. When approved, this standard would replace ISO 10011-1, ISO 10011-2, and ISO 10011-3 on quality auditing and ISO 14010, ISO 14011, and ISO 14012 on environmental auditing. A Joint Working Group (JWG) was established comprising experts from both TC 176 and TC 207 to develop the new standard, ISO 19011, Guidelines on Quality and/or Environmental Management Systems Auditing, and to incorporate lessons learned from efforts to improve compatibility between ISO 9001/9004 and ISO 14001/14004, the standards for quality and environmental management systems, respectively. Work is proceeding on the development of ISO 19011 with an expected completion in the spring of 2001.

INTRODUCTION

This paper discusses the combined auditing standard, ISO 19011:2002, *Guidelines on Quality and/or Environmental Management Systems Auditing.* It includes a description of the standard, a discussion of relevant issues addressed during its development, and a summary of its current status. Following the approval of the ISO 14001 and ISO 14004 environmental management systems (EMS) standards and the start of a revision to the ISO 9000 quality management systems (QMS) standards, there was considerable interest by ISO in increasing the compatibility between the EMS and QMS standards. Early in the discussions, it became clear that the similarities among the existing EMS and QMS auditing standards would make them a prime candidate for integration.
The Joint Working Group (JWG) was created by ISO to develop the new standard. The JWG would have co-conveners, one from TC 176 and one from TC 207, and experts would be drawn from both technical committees. Because this venture had never been attempted by ISO before, the ground rules for operating the standard-setting process also had to be revised. Both TC 176 and TC 207 would participate fully in the process. Ballots would be sent to national member bodies for both technical committees, but ISO's rule of "one country, one vote" would require that both TC's agree on the vote for a particular ballot. Otherwise, a country's vote would not be counted. To ensure that a consensus position is reached in the USA, the U.S. Technical Advisory Groups (TAGs) to TC 176 and TC 207 formed a Liaison Group with representatives from TAG 176/Subcommittee 3 on Quality Auditing and TAG 207/ Subcommittee 2 on Environmental Auditing to formulate the USA position on ballots.

In November 1998, the first meeting of the JWG to develop a common auditing standard was held in The Hague, The Netherlands. Experts from TC 176 and TC 207 representing 34 countries attended that meeting with the purpose of charting the development process for the new standard. From the outset, the stronger experience was with the quality auditing standards. The environmental auditing standards had been published only for a little over two years and there wasn't much experience in their use. While very similar, there were some distinct differences between the quality auditing philosophy and that of environmental auditing. Issues getting early attention included auditor competency, usability by small-to-medium enterprises (SMEs) and developing countries, and the structure of the standard.

By the spring of 1999 and the second JWG meeting in Buenos Aires, Argentina, an initial Working Draft (WD.1) of the standard had emerged. Discussions were held at the TC 207 meeting in Seoul in June 1999 and at the TC 176 meeting in San Francisco in September 1999, which resulted in the first Committee Draft (CD.1) of ISO 19011. CD.1 was balloted in late 1999 and more than 1400 comments from 35 countries were received by the JWG Secretariat by the end of February 2000.

The JWG met in Berlin, Germany, in March 2000, to address the comments on CD.1. The JWG was divided into two sub-groups, one to address comments on the structure and process aspects of the standard, and one to address the comments on auditor competency. Each sub-group had about half of the comments. After considerable debate, the draft for CD.2 emerged and was balloted for comments in April 2000. The comments were received in August and were addressed by the JWG in Cancun, Mexico in September. The Cancun meeting produced CD.3 which subsequently distributed for comments in late fall 2001. The international comments on CD.3 will be addressed in Sydney, Australia, in March 2001. Depending on the comments and ballot results, the Sydney meeting should produce a Draft International Standard for a six month ballot among the ISO member countries. The goal is to publish ISO 19011 as an international consensus standard in early 2002.

PURPOSE OF THE STANDARD

ISO 19011 is intended to provide guidelines for auditing ISO 9001-based quality management systems and ISO 14001-based environmental management systems. The standard will replace the following current standards:

- ISO 10011-1, -2, -3, *Guidelines for Auditing Quality Systems*
- ISO 14010, *Guidelines for Environmental Auditing - General Principles*
- ISO 14011, *Guidelines for Environmental Auditing - Audit Procedures - Auditing of Environmental Management Systems*
- ISO 14012, *Guidelines for Environmental Auditing - Qualification Criteria for Environmental Auditors*

ISO 19011 reflects the changes made to ISO 9001:2000, *Quality Management Systems - Requirements*, which is scheduled to publication later this year, including the new business model for the standard. ISO 19011 is intended to apply to both internal and external auditing, and may be used as part of auditor certification and training.

STRUCTURE OF ISO 19011

The structure of ISO CD.3 19011 is as follows:

0 Introduction
1 Scope
2 Normative References
3 Terms and Definitions
4 Principles of Auditing
5 Managing an Audit Program
6 Audit Activities
7 Competence of Quality and/or Environmental Management System Auditors

The standard also contains an informative annex on examples of the evaluation process for audit team selection. The standard also includes several diagrams to aid users in understanding and using the guidance.

ISO 19011 is a guideline standard which means its use is not mandatory unless it is invoked as part of a multiple party agreement, such as contract or other legal agreement. As a guideline standard, its implementation is generally not auditable because the elements of the standard are not requirements and because there may be others ways of accomplishing the same objectives.

ISO 19011 is generally organized in two parts: Clauses 4 through 6 address the process of planning, conducting, and evaluating audits and Clause 7 addresses issues pertaining to auditor competence and selection. Clause 0, Introduction, assists the reader in understanding the reason for the standard and who might use it. Clause 1, Scope, defines the scope and applicability of the standard which extends beyond QMS and EMS auditing.

THE AUDIT PROCESS

Clause 4 - Principles of Auditing

The standard provides a brief summary of auditing principles in Clause 4. These principles should be used to drive the establishment and implementation of the audit process for an organization. Key among the principles cited for auditor behavior are:

- ethical conduct - the foundation of professionalism,
- fair presentation - the obligation to report truthfully and accurately, and
- due professional care - application of reasonable care in auditing.

Two other principles of auditing relate to the audit process primarily. They are:

- independence - the basis for impartiality and objectivity of the audit conclusion, and

- evidence - the rational basis for reaching audit conclusions.

Clause 5 - Managing an Audit Program

Clause 5 provides guidance for those who need to establish and maintain an ongoing set of audits for an organization. The standard utilizes the Plan-Do-Check-Act cycle to define the audit program. Some of the key actions addressed are:

- establishing the objectives and extent of the audit program,
- establishing the responsibilities, resources, and procedures,
- ensuring the implementation of the audit program,
- monitoring and reviewing the audit program to improve its efficiency and effectiveness, and
- ensuring that appropriate program records are maintained.

Because the standard may be applied to internal and external auditing, the objectives and extent of the audit program is a critical early step in defining the audit program for a particular organization or application. Any audit program must be managed by managers having appropriate authorities and resources to implement the program.

The audit program must also address the possibility of "combined audits" and "joint audits." A "combined audit" occurs when a QMS and EMS are audited at the same time by the same audit team. A "joint audit" occurs when two audit teams cooperate to audit an organization during the same period with one team auditing the QMS and the other team auditing the EMS.

The audit program must be monitored and reviewed to ensure its ongoing effectiveness in meeting the needs of the organization. Adjustments to the audit program should be made when needed in order foster improvements.

Clause 6 - Audit Activities

Clause 6 describes the six general steps in planning and conducting an audit. The steps include:

- initiating the audit,
- initial document review,
- preparing for on-site audit activities,
- performing on-site audit activities,
- reporting the audit results, and
- audit completion (including any follow-up activity that may be needed).

Initiating an audit requires consideration of several factors, including:

- having defined audit objectives,

- confirmation that the audit is feasible, and
- establishing a satisfactory audit team.

Once established, the audit team will review any available documents pertaining to the audit and prepare for the on-site phase of the audit, including the logistics required and arrangements (such as travel) to be made, specific assignments to audit team members, etc.

Whether a QMS or EMS audit, the on-site activities are similar and include:

- opening meeting with the auditee,
- roles and responsibilities of guides (as needed),
- collection and verification of information,
- audit findings,
- communication with the audit client and auditee,
- preparation of the closing meeting, and
- closing meeting.

Reporting on the audit results is a critical step and must accurately reflect what transpired during the audit. The key is to address the extent of conformance to the audit criteria, the effectiveness of the management system implementation, and the ability of the management review process to assure the continuing suitability and effectiveness of the management system. This is a significant difference from QMS audit criteria in the past when auditors frequently commented on the suitability and effectiveness of the management system itself. This was inappropriate for two reasons: (1) management is responsible for assessing the value (i.e., "suitability and effectiveness") of the management system and (2) the auditors may lack critical knowledge about the organization's operations in order to assess the value of the management system.

The standard provides for audit follow-up as needed to confirm that all non-conformances have been addressed.

COMPETENCE OF QUALITY AND/OR ENVIRONMENTAL MANAGEMENT SYSTEM AUDITORS

It is a given that auditors must be competent to perform their assigned tasks. The extent to which ISO 19011 should address auditor competence has been the principal source of debate among the JWG members. There is no question that guidance is needed to define the general areas of competence based on:

- education,
- audit experience,
- auditor training,
- work experience, and
- personal attributes.

The guidance provides for knowledge, skills, and personal attributes needed for an audit team leader as well and also addresses the unique competence needed for combined audits.

The biggest issue is whether or not the standard should specify minimum levels of training or work experience. Sentiments have been strong that this is needed, but representatives of some developing countries have expressed concern that the requirements are too burdensome for them. In CD.3, Clause 7 contains a table of "recommended education, training, and work and audit experience." While ISO 19011 is officially a guideline, inclusion of this table in the standard would imply that these are minimum experience levels. The USA has been concerned that this table reflects experience levels appropriate to certification or registration audits by third parties and that some users could be influenced to apply the table to other audit situations, including internal audits and second-party supplier audits. The USA has proposed that the table be deleted or, as a best case, moved to an Informative Annex of the standard with additional examples that cover the full range and scope of auditing to be addressed by the standard. Each national standards body would be responsible for defining the minimum experience levels appropriate for auditors, recognizing that there are differences between the major industrialized nations and the developing countries in terms of capabilities.

The standard does define general areas of competence that should be considered when determining the suitability of an auditor. These include competence in:

- audit procedures, methods, and techniques;
- management systems and related documents;
- organizational situations; and
- relevant laws, regulations and other requirements.

The standard also provides guidance for the maintenance of auditor knowledge and skills, including continuing professional development and auditing ability. This would be assured through implementation of an auditor evaluation process.

CONCLUSIONS

ISO 19011 CD.3 has accomplished several important objectives in the development of the standard:

- the contents of ISO 10011-1, -2, and -3 have been fully incorporated into the standard;
- the contents of ISO 14010, ISO 14011, and ISO 14012 have been fully incorporated into the standard;
- the interests of the environmental and quality communities have been successfully integrated into one document; and
- the new standard has been made easier to use with a logical structure and with a number of diagrams and examples.

While some critical issues remain to be resolved, the USA remains optimistic that they will be resolved in Sydney, Australia, in March 2001 and that a Draft International Standard will emerge for approval and publication by early 2002.

REFERENCES

ISO 19011/CD.3, *Guidelines on Quality and/or Environmental Management Systems Auditing*. International Organization for Standardization, Geneva, Switzerland (October 2000).

ANSI/ISO/ASQ Q9001:2000, *Quality Management Systems - Requirements.* American National Standards Institute, New York, NY (December 2000).

THE ROLE OF FIELD AUDITING IN ENVIRONMENTAL QUALITY ASSURANCE MANAGEMENT

Mr. Daniel Claycomb, Director of Geosciences at Environmental Standards, Inc., Valley Forge, Pennsylvania

Abstract — Environmental data quality improvement continues to focus on analytical laboratory performance with little, if any, attention given to improving the performance of field consultants responsible for sample collection. Many environmental professionals often assume that the primary opportunity for data error lies within the activities conducted by the laboratory. Experience in the evaluation of environmental data and project-wide quality assurance programs indicates that an often-ignored factor affecting environmental data quality is the manner in which a sample is acquired and handled in the field. If a sample is not properly collected, preserved, stored, and transported in the field, even the best of laboratory practices and analytical methods cannot deliver accurate and reliable data (i.e., bad data in equals bad data out). Poor quality environmental data may result in inappropriate decisions regarding site characterization and remedial action.

Field auditing is becoming an often-employed technique for examining the performance of the environmental sampling field team and how their performance may affect data quality. The field audits typically focus on: (1) verifying that field consultants adhere to project control documents (e.g., Work Plans and Standard Operating Procedures [SOPs]) during field operations; (2) providing third-party independent assurance that field procedures, quality assurance/quality control (QA/QC) protocol, and field documentation are sufficient to produce data of satisfactory quality; (3) providing a "defense" in the event that field procedures are called into question; and (4) identifying ways to reduce sampling costs.

Field audits are typically most effective when performed on a "surprise" basis; that is, the sampling contractor may be aware that a field audit will be conducted during some phase of sampling activities but is not informed of the specific day(s) that the audit will be conducted. The audit should also be conducted early on in the sampling program such that deficiencies noted during the audit can be addressed before the majority of field activities have been completed. A second audit should be performed as a follow-up to confirm that the recommended changes have been implemented.

A field auditor is assigned to the project by matching, as closely as possible, the auditor's experience with the type of field activities being conducted. The auditor uses a project-specific field audit checklist developed from key information contained in project control documents. Completion of the extensive audit checklist during the audit focuses the auditor on evaluating each aspect of field activities being performed. Rather than examine field team performance after sampling, a field auditor can do so while the samples are being collected and can apply real-time corrective action as appropriate.

As a result of field audits, responsible parties often observe vast improvements in their consultant's field procedures and, consequently, receive more reliable and representative field data at a lower cost. The cost savings and improved data quality that result from properly completed field audits make the field auditing process both cost-effective and functional.

INTRODUCTION

A commonly overlooked factor in developing and implementing environmental quality assurance systems is providing a means for verifying that field personnel are conducting each aspect of field investigation activities in compliance with project control documents. Environmental professionals commonly assume that the primary opportunities for adverse impact to environmental data quality lie within the walls of the laboratory. Consequently, quality assurance programs focus on laboratory operations and consist of developing detailed laboratory analytical procedures, evaluation of laboratory blind duplicate and performance evaluation sample results, stringent laboratory auditing programs, and rigorous validation of laboratory data. Although these laboratory quality assurance activities are necessary and valuable, the relevance of their findings is limited unless the environmental samples were properly collected, stored, and transported and proper sample custody was maintained.

The preparation of project control documents for the implementation of field activities (*e.g.*, work plans, health and safety plans [HASPs], sampling and analysis plans [SAPs], standard operating procedures [SOPs], *etc.*) is only the beginning of the quality assurance process for field investigations. It is critical that all field personnel review and follow the provisions of the control documents. To make sure that field personnel are not deviating from the approved procedures specified in the control documents (or that field personnel are justified in deviating from the procedures and are appropriately documenting the deviations), it is important to conduct independent third-party field audits of field sampling teams.

Field audits are conducted for three primary purposes: (1) to verify that procedures identified in the project control documents are adhered to during field operations; (2) to provide verification from an independent organization that field procedures, quality assurance/quality control (QA/QC) protocol, and field documentation are sufficient to produce data of satisfactory (usable) quality; and (3) to provide project stakeholders with a "defense" in the event that field procedures are called into question.

FIELD AUDITING PROCEDURES

Typically, field audits are done on a "surprise" basis; that is, the sampling organization is aware that a field audit will be conducted during some phase of sampling activities but is not informed of the specific day(s) that the audit will occur. Ideally, the audit is conducted early in the field program such that deficiencies noted during the audit can be addressed before the majority of field activities have been completed. Often, a second audit is conducted later in the program to confirm that the recommended changes have been implemented. Rather than examine field team performance after sampling, a field auditor can do so while the samples are being collected and can apply real-time corrective action as appropriate.

Once the need for a field audit has been determined, a field auditor is assigned to the project by matching, as closely as possible, the auditor's experience with the type of field activities being conducted. The designated field auditor then reviews the applicable field event control documents. A project-specific field audit checklist is developed based on the information in these documents. The multi-page checklist follows general headings (such as, pre-task planning, field documentation, sample containers, sampling activities, QA/QC samples, chain-of-custody, decontamination, sample packaging, waste management, and health and safety) to group field activities. Completion of an extensive audit checklist during the audit focuses the auditor on evaluating each aspect of field activities being performed. When developing the checklist, the auditor also reviews field team performance with the client for input regarding any field team deficiencies that the client has observed or about which other involved parties (*e.g.* the laboratory) may have informed the client.

On the day of the audit, the auditor should arrive at the project site at the time the field crew arrives; this will provide the auditor the opportunity to communicate the purpose of the visit and will allow observation of each aspect of field activities in their entirety. During introductions, the auditor describes how the audit will proceed during the course of field activities and explains that the auditor's role is not an adversarial one and that the goal of auditor, as part of the project team, is to collect the highest quality of data possible so that the data accurately represent actual site conditions.

The field crew must also be aware that, although the auditor will attempt to minimize interruptions to field activities, the auditor's presence and questioning throughout the day will likely slow the pace of field activities. In some cases, there may be delays while corrective actions (in response to the auditor observing a significant deviation or deficiency) are discussed. The auditor should be given the authority to act on behalf of the client and to delay and/or cease field activities until significant deficiencies have been addressed.

Upon completion of the field audit, the field team leader attends a debriefing meeting (typically held the same day as the audit at the end of the day) with a client representative and the field auditor to discuss the auditor's observations and recommendations. It is best that each of these parties be present so that audit findings can be openly discussed and corrective actions can be determined and implemented immediately. If all parties cannot meet at this time, the auditor should review each of his findings with the field team leader, should indicate that he will present these same finding to the client, and should stipulate that any corrective action will be communicated as soon as possible to the field team leader by the client.

As soon as possible following the audit, the auditor prepares a field audit report that summarizes audit events, presents deficiencies observed during the audit, and provides recommendations to address the observed deficiencies. In addition, the report should identify the type and source of deviations from the control document of concern. Due to the nature of a field audit, some critical statements will be presented in the report. The statements should be based on observations made in the field and should address only those areas in which project field team deficiencies were noted and where changes may be appropriate. An exhaustive list of the activities performed in accordance with the project control documents and observed to be in compliance with standard industry protocol are typically not presented in the audit report.

WHICH SAMPLING PROGRAMS AND FIELD ACTIVITIES SHOULD BE AUDITED

The need, reason, and usefulness of conducting field audits are not limited to certain types of clients, projects, or sampling activities. Fields audits have been proven to be a valuable part of sampling programs conducted at manufacturing facilities, former landfills, wastewater treatment plants, and compressor and metering stations along natural gas pipelines. There is a diverse range of reasons why a particular site is undergoing an environmental assessment. Some sites are involved in property transactions (where a potential buyer may wish to assess environmental liabilities of a property before entering a purchase agreement, or a potential seller make want to know what impacts his/her operations at the site may have had before the property is put on the market, or a property owner may wish to establish baseline environmental conditions at his/her site before the site is leased to another party); some sites are under administrative consent orders or memorandums of agreement with federal or state regulatory agencies; others may be undergoing assessment and remediation under a voluntary cleanup program; and yet others are being considered for redevelopment under a Brownfields program. No matter what the reason for the assessment or remedial activity, project stakeholders deserve and expect that dollars spent on environmental assessment activities generate accurate and reliable data. The proper preparation for and implementation of field sampling activities starts the data generation process.

The types of media of concern and the resultant field activities conducted at sites like those described above will vary a great deal. Sampling programs may require field personnel to collect multi-media samples, possibly including soil (both surface and subsurface), groundwater, surface water, sediment, air, surface wipe, wastewater effluent, or chip samples. The methods used to collect these sample may include drilling operations (such as rotosonic, air rotary, hollow stem auger, and Geoprobe[â]), hand sampling tools, (such as augers, bailers, trowels, chisels, *etc.*) motorized equipment (electric sampler for instance), pumps (such as peristaltic, submersible, centrifugal, and electrical), and trenching and excavation activities under personal protection levels B, C, and D.

If one considers the many variables involved in a sampling program (*e.g.*, the types of sites, the different media and constituents of concern at each site, the purposes and objectives of the sampling programs, the array of sampling equipment and techniques, the implications of regulatory and contractual terms and conditions, strict and complete documentation requirements, and unforgiving project schedules), one can quickly realize that there are enormous opportunities for poorly executed field activities to have a negative impact on sample data quality and integrity. One way to minimize the potential for these negative impacts is to have an experienced, qualified, independent, third-party field auditor develop and implement a field auditing program.

BENEFITS OF FIELD AUDITS

Each of the parties involved in the field auditing process realizes significant benefits from having field audits conducted. Clients achieve improvements in their consultant's field procedures and, consequently, receive more reliable and representative field data on which to base important decisions. There is a cost control aspect that is addressed by the auditing process as well. The audits help to assess and to streamline an efficient use of project resources, to immediately locate and correct deficiencies, to verify that the client is getting what they contracted for, and to make sure the work is done once and done right. In terms of liability control, field audits can be used to support litigation activities, to help ensure that proper health and safety protocols are followed, and to confirm that properly trained and appropriately experienced field personnel have been assigned to the project.

The audited field contractors typically are open-minded, view the field auditor's comments as constructive, and consider the audit a good learning experience. Field auditors benefit by expanding their field experience and capabilities by observing other organization's field methods and by being continually exposed to the environmental industry's most up-to-date and "hi-tech" equipment and technologies.

CONCLUSIONS

As a result of field audits, responsible parties often observe vast improvements in their consultant's field procedures and, consequently, receive more reliable and representative field data at a lower cost. The cost savings and improved data quality that result from properly completed field audits make the field auditing process both cost-effective and functional.

AUTOMATED DATA REVIEW (ADR), CONTRACT COMPLIANCE SCREENING (CCS), AND ENVIRONMENTAL DATABASE MANAGEMENT SYSTEM (EDMS) SOFTWARE APPLICATIONS FOR THE SACRAMENTO DISTRICT FORT ORD PROJECT

Tony Blake, Nicole Ortega, Pam Wehrmann, John Esparza, Richard M. Amano

Abstract — This presentation is an overview of the Contract Compliance Screening (CCS), Automated Data Review (ADR), and Environmental Database Management System (EDMS) software programs developed by Laboratory Data Consultants, Inc. under contract to the Army Corps of Engineers, Sacramento District for the Fort Ord RI/FS project. The software programs use an electronic data deliverable (EDD) format based upon data elements originally documented in the Implementation Guide for the Department of Energy Environmental Management Electronic Data Deliverable Master Specification (DEEMS). The software was developed on a Microsoft ACCESS 97 platform. Customized modules perform automated data review (EPA Level 3) and provide the user with discrete data qualification. The qualified data is exported into a master database for overall project use.

The EDD format includes QA/QC batch links and routine accuracy and precision parameters such as surrogate, matrix spike, and laboratory control sample recoveries. In addition, initial and continuing calibration and GC/MS tuning data are delivered in this format. Development of the EDD integrated these data elements required by end users with consideration for the current data deliverable capabilities of commercial laboratories.

The CCS software verifies the completeness and compliance with the EDD format. The software references a project specific library built upon the QAPP in verifying compliance and completeness. EDD deficiencies are detailed in an outlier report. Access to the EDD file in table format allows for quick and easy correction of errors.

The ADR software is initiated by the data user (i.e., Army Corps chemist, prime contractor, etc.) to review analytical data based upon project specific criteria. Upon execution of the program, data is qualified using standard Army Corps/EPA data flags and exported into a master database. Command buttons generate reports such as a rejected data table, method blank contamination, surrogate outliers, etc. Forms and view screens also provided on-line review of data qualifiers.
The Environmental Database Management System (EDMS) compiles the validated data downloaded from the ADR system. The database program has user functions which allows for comparison of primary data versus QA split lab data, comparison of results against project action limits or PRGs/MCLs, and calculates the completeness values for each test over any period of time. The four types of completeness values include contract, analytical, technical, and field sampling completeness.

In conclusion, the CCS, ADR, and EDMS software programs were developed as tools to support technical staff in the evaluation of analytical chemistry data using an

expedited and cost effective automated process. The EDD provides a standardized format. This format allows for streamlining at the laboratories to produce deliverables which can be verified immediately for completeness and compliance against project criteria using the CCS software. The EDMS allows the data end user to efficiently evaluate large data sets for key indicators and ultimately determine the usability of the data.

Introduction

This poster presentation is an overview of the Contract Compliance Screening (CCS), Automated Data Review (ADR), and Environmental Database Management System (EDMS) software programs developed by Laboratory Data Consultants, Inc. under contract to the Army Corps of Engineers, Sacramento District for the Fort Ord RI/FS project. The software programs use an electronic data deliverable (EDD) format based upon data elements originally documented in the Implementation Guide for the Department of Energy Environmental Management Electronic Data Deliverable Master Specification (DEEMS). The software was developed on a Microsoft ACCESS 97 platform. Customized modules perform automated data review (EPA Level 3) and provide the user with discrete data qualification. The qualified data is exported into a master database for overall project use.

Summary

The Electronic Data Deliverable (EDD) format is divided into a three table relational structure. The tables are linked with selected key fields. The tables are divided into a Results Table, a Sample Table, and a Instrument Calibration Table. These files include QA/QC batch links and routine accuracy and precision parameters such as surrogate, matrix spike, and laboratory control sample recoveries and initial and continuing calibration and GC/MS tuning data. Development of the EDD integrated these data elements required by end users with consideration for the current data deliverable capabilities of commercial laboratories. The following is the list of field names in the three tables.

Results Table (A1)	**Instrument Table (A2)**	**Sample Analysis Table (A3)**
Client_Sample_ID	Instrument_ID	Project_Number
Lab_Analysis_Ref_Method_ID	QC_Type	Project_Name
Analysis_Type	Analyzed	Client_Sample_ID
Lab_Sample_ID	Alternate_Lab_Analysis_ID	Collected
Lab_ID	Lab_Analysis_ID	Matrix_ID
Client_Analyte_ID	Lab_Analysis_Ref_Method_ID	Lab_Sample_ID
Analyte_Name	Client_Analyte_ID	QC_Type
Result	Analyte_Name	Shipping_Batch_ID
Result_Units	Run_Batch	Temperature
Lab_Qualifiers	Analysis_Batch	Lab_Analysis_Ref_Method_ID

Results Table (A1)	**Instrument Table (A2)**	**Sample Analysis Table (A3)**
Detection_Limit	Lab_Reporting_Batch	Preparation_Type
Detection_Limit_Type	Relative_Percent_Standard_Deviation	Analysis_Type
Retention_Time	Percent_Difference	Prepared
Analyte_Type	Several fields for BFB/DFTPP ratios and peak ID	Lab_ID
Percent_Recovery		QC_Level
Relative_Percent_Difference		Result_Basis
Rewporting_Limit		Total_Or_Dissolved
Reporting_Limit_Type		Dilution
Reportable_Result		Handling_Type
		Handling_Batch
		Laechate_Date
		Percent_Moisture
		Method_Batch
		Preparation_Batch
		Run_Batch
		Analysis_Batch
		Lab_Reporting_Batch
		Lab_Receipt
		Lab_Reported

The CCS software verifies the completeness and compliance with the EDD format. The software references a project specific library built upon the Quality Assurance Project Plan (QAPP) in verifying compliance and completeness. EDD deficiencies are detailed in an outlier report. Access to the EDD file in table format allows for quick and easy correction of errors.

The ADR software is initiated by the data user (i.e., Army Corps chemist, prime contractor, etc.) to review analytical data based upon project specific criteria. Upon execution of the program, data is qualified using standard Army Corps/EPA data flags and exported into a master database. Command buttons generate reports such as a rejected data table, method blank contamination, surrogate outliers, etc. Forms and view screens also provided on-line review of data qualifiers. See Attachment 1 for an example of user screens.

The Environmental Database Management System (EDMS) compiles the validated data downloaded from the ADR system. The database program has user functions which allows for comparison of primary data versus QA split lab data, comparison of results against project action limits or PRGs/MCLs, and calculates the completeness values for each test over any period of time. The four types of completeness values include contract, analytical, technical, and field sampling completeness. See Attachment 2 and 3 for an example of user screens.

In summary, the CCS, ADR, and EDMS software programs were developed as tools to support technical staff in the evaluation of analytical chemistry data using an expedited and cost effective automated process. The EDD provides a standardized format. This format allows for streamlining at the laboratories to produce deliverables which can be verified immediately for completeness and compliance against project criteria using the CCS software. The EDMS allows the data end user to efficiently evaluate large data sets for key indicators and ultimately determine the usability of the data.

Attachment 1

QC Outlier Report: Continuing CalibrationVerification

Analysis Batch : msv0309?3a   Analysis Method : 8260B   Analysis Date : 03/24/1999
Lab Reporting Batch : P909410   Lab ID: SAL-Pet

	Calibration Result		Project Limits				
				Positive Percent Difference		Negative Percent Difference	
Analyte Name	Relative Response Factor	Percent Difference	Relative Response Factor	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Chloroethane	0.0294	7.7	0.05		25.0	50.0	25.0
Dichlorodifluoromethane	0.295	-27.7			25.0	-50.0	-25.0

Associated Samples	
Client Sample ID	Lab Sample ID
9537E0122534	P909410-24
9537E0122544	P909410-25
9537E0122055	P909410-26
9537MO131027	P909410-19
9537MO131037	P909410-20
9537MO131047	P909410-21
9537MO221055	P909410-22

Figure 1 **Quality Control Outlier Report – The ADR program has built in QC outlier reports which summarizes calibration deficiencies using the project specific method and validation criteria.**

Data Qualification Report

(All Qualifiers)

Client Sample ID : 9537E0122534   Lab Report Batch : P909410   Lab ID : SAL-Pt
Sample Date : 03/15/1999   Analysis Type: *RES*   Sample Matrix : AQ
Lab Sample ID: P909410-14

Validated By / Date : ....   Approved By / Date : ....

Analyte Name	Result	Result Units	Lab Qual	Rep Res	Overall Val Qual	Temp	HT	MB	LCS	MS	Lab Dup	Surr	Rep Limit	Field QC	Tune	IC	ICV	CV/CCV
Analysis Method : *6010B*																		
Potassium	3000	ug/l		YES	J					J								
Analysis Method : *8260B*																		
Bromodichloromethane	0.0709	ug/l	J	YES	J+							J+						
Chloroform	0.0750	ug/l	J	YES	UJ							J+		L				
Dibromochloromethane	0.0560	ug/l		YES	J							J						
Freon 113	0.222	ug/l	J	YES	J+							J+						
Methylene chloride	0.137	ug/l	J	YES	UJ							J+		L				
Tetrachloroethene	0.152	ug/l		YES	J							J						

Figure 2 **Data Qualification Summary Report – The ADR program provides a summary of qualified data itemizing each quality control area.**

Attachment 2

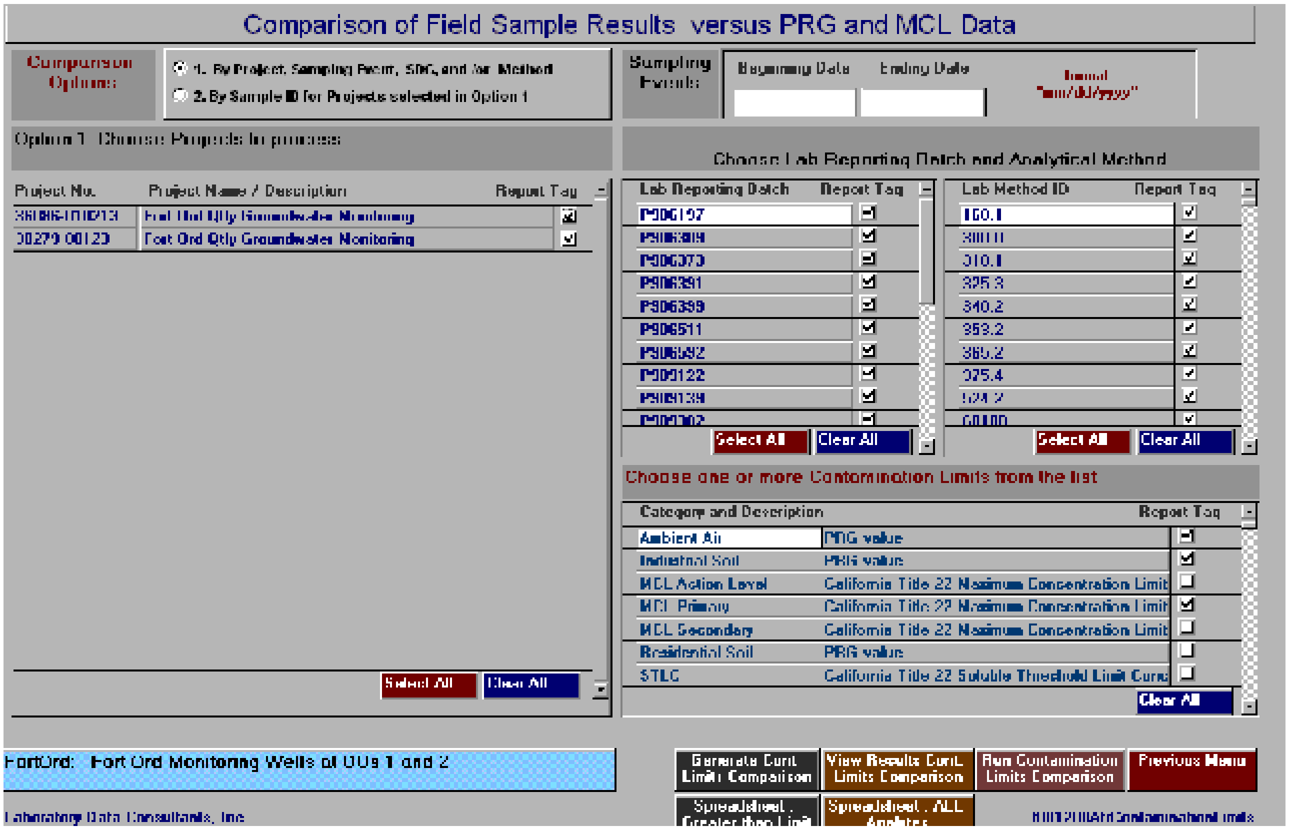


Figure 3 **Comparison of Analytical Results vs PRGs and MCLs – The EDMS application provides user tools to allow for the comparison of field sample results against project specific PRGs and MCLs. The data can be filtered and selected based on many unique criteria.**

Attachment 3

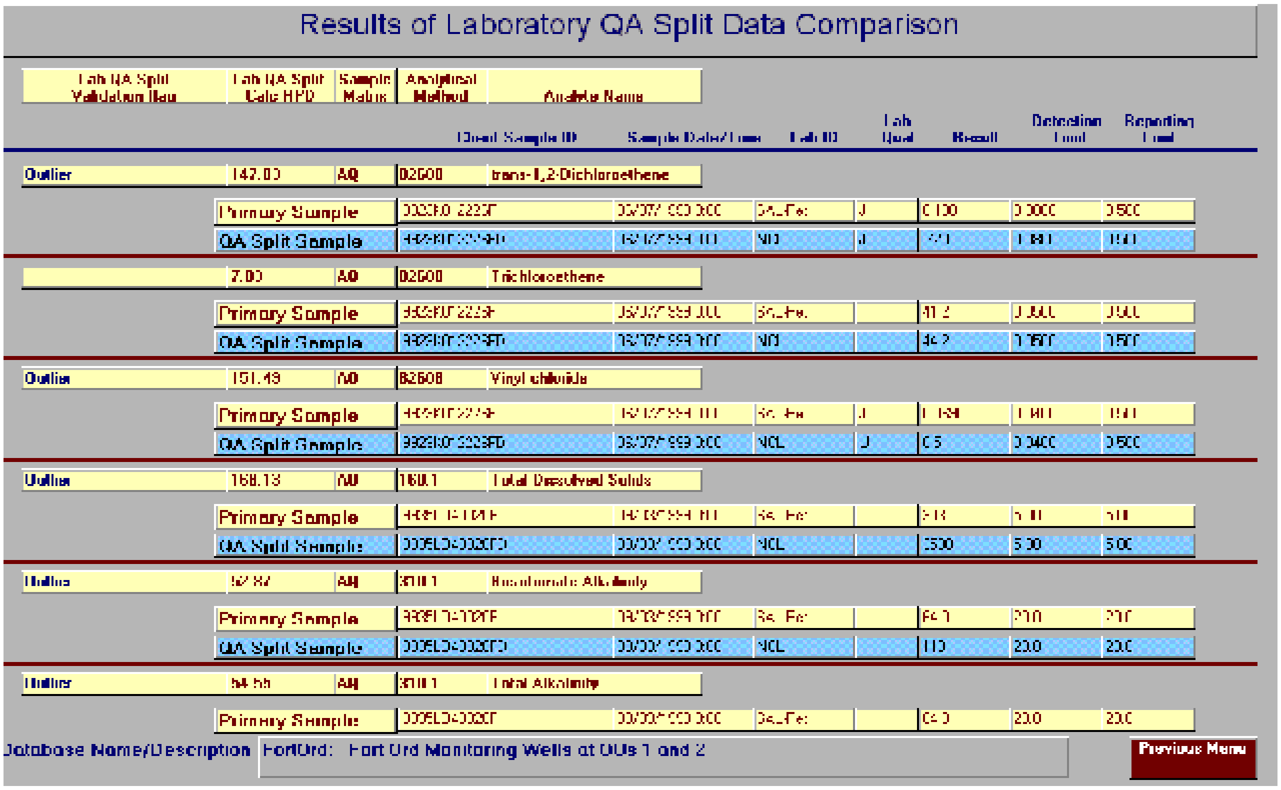


Figure 4 **Laboratory QA Split Sample Comparison – The EDMS program allows the user to compare QA split sample results generated from two different laboratories.**

IMPORTANT CONSIDERATIONS IN SELECTING AND IMPLEMENTING A LIMS IN WATER QUALITY TESTING LABORATORY

Kim Ryals, Elizabeth Turner, Christine Paszko, and Don Kolva
Accelerated Technology Laboratories and Washington Aqueduct

Abstract — Today's environmental laboratory faces numerous challenges from enhanced regulatory oversight to decreasing costs per tests to numerous laboratory accreditations that are offered and/or required. Selecting the LIMS that will not only "fit" your laboratory is important, but as important is a system that has the flexibility to conform to the changes that will be required by the laboratory over the years. Not only in terms of reporting, but also in terms of the ability to integrate new instrumentation, integrate new calculations, new screens and the ability to integrate with future software.

In selecting a LIMS, it is important to have a good understanding of the requirements of both current and future laboratory needs. Equally as important in selecting the functionality that matches the laboratory requirements is selecting a technology platform that is easy to manage, a market leader and utilizes open architecture. The laboratory chose Microsoft SQL Server as the database engine. The selection of Microsoft SQL Server provides seamless integration with the Microsoft Office Suite (Word, Excel, Access, PowerPoint) which is used in the laboratory. This allows users to export directly from the LIMS to any of the programs in the suite and visa versa. This synergy enhances the flexibility of the LIMS.

Many laboratories produce a request for proposal that includes a list of features and functionality that is required to help automate the laboratory and to provide a system to integrate the various data systems and reporting within the laboratory. Some laboratories also include hardware in their request for proposal and ask the vendor to deliver a complete system, hardware and software. This provides the LIMS vendor with a clear understanding of what the primary needs of the laboratory are currently and in the future. There are many features in a LIMS, however the primary functionality includes; sample tracking, data entry, sample scheduling, QA/QC, electronic data entry, chemical and reagent inventory and personnel and equipment management. After the proposals had been reviewed, the top three vendors were invited in, to provide a scripted demo of the features and functions that were important to the laboratory. Other features that help increase productivity and efficiency include the use of bar codes, data loggers, instrument integration and specialized software modules such as cost accounting/time tracking. This demonstration is highly beneficial because it gives laboratory personnel the opportunity to see how the software will function and they can begin to visualize how the LIMS can assist them in their jobs.

Implementing a LIMS begins with the installation and configuration of the server (Dell PowerEdge 2400), installation of the LIMS software on the server and client machines, and creating custom reports for end-users. The installation phase also

involved configuring and integrating label printers (to print barcodes) with the LIMS, hand held CCD scanners, data loggers (for remote collection of field data which can then be uploaded to the LIMS). In addition, integration of several high throughput instrumentation (Agilent ICP-MS, Tekmar-Dohrman TOC, Varian Saturn GC-MS, Agilent GC-MS, Dionix IC) was another phase of the project. More laboratories are turning to integration of their instrumentation to avoid manual entry of results into the LIMS and also to avoid transcription errors. Finally there is a verification and training phase. In verification the LIMS trainers and laboratory personnel review the feature and functions utilizing a checklist to ensure that all the components of the installation are in place and operating accordingly. Next the database administrators and end-users receive training manuals and go over examples in the manuals followed by a questions and answer period. Once the LIMS is installed, users have the ability to participate in follow-up training courses offered by the LIMS vendor and to attend user group meetings to continually learn about new features and keep abreast of the latest technology.

Introduction

Selecting a LIMS for the environmental testing laboratory requires a solid understanding of what tasks are performed by the laboratory currently and an idea of which tasks the laboratory may want to perform with the LIMS in the future. This is important because demands made upon the laboratory will change over time and will require a LIMS to provide flexibility to accommodate these needs.

A detailed LIMS Request for Proposal (RFP) was presented to Accelerated Technology Laboratories together with several other LIMS vendors. Each vendor was asked to answer a series of questions relating to the WAD LIMS specifications, the company, support options, LIMS experience and references. The specifics of the RFP include a detailed description of the functionality of the various features or modules of the LIMS. The RFP began with questions on Sample Tracking, Data Entry, Sample Scheduling, QA/QC, Electronic Data Transfer, Chemical and Reagent Inventory, and Personnel and Equipment Management. Other key elements of the RFP included requests for information on statistical capabilities, data loggers to upload data to the LIMS, bar-coding, instrument integration, time tracking software for cost accounting, custom report creation and integration with the laboratory's SCADA system. The RFP also requested the LIMS vendor to provide the hardware (server for the LIMS) and all necessary software tools to manage the server, including Microsoft SQL Server Licensees and back-up software. Another section of the RFP focused on the expertise of the LIMS vendor and the personnel responsible for the installation and implementation. The WAD laboratory requested the LIMS vendor to provide a "turn-key" system.

The LIMS having the highest score on the LIMS questionnaire were invited to visit the laboratory and provide an on-site demo based on a script prepared by the laboratory. The demos were viewed by laboratory management and staff to gain a thorough understanding of how the LIMS works and if there is a match in the way in which the LIMS operates. Once the feedback from the laboratory is gathered, the scores tallied and the cost proposals reviewed, the laboratory selects the LIMS that best fits its operations and the needs of an environmental testing laboratory.

It is important for the LIMS vendor to understand how the samples flow through the laboratory. The figure 2. depicts the typical sample flow through the laboratory at the WAD laboratory.

Installation

Accelerated Technology Laboratories, Inc. was the successful bidder and Sample Master® Pro LIMS best matched the specifications and the ATL staff had the expertise required by the WAD laboratory. Before the installation could begin, all hardware and software systems were ordered from the respective vendors:

WAD Configuration

Server Hardware:

- Dell Server with 17" Monitor
- Dual Pentium III 933 MHz processors
- Integrated 3Com 10/100 Ethernet controller
- 512 MB RDRAM (2 RIMMS)
- Three (3) 18 GB SCSI harddrives
- RAID 5 Parity
- 20/48x CD-ROM Drive
- 3.5" 1.44 MB Floppy drive
- 40 GB DDS-4 Tape Drive with 10 tapes

Data loggers (2) from Intermec

Network: Ethernet network, with the NT 4.0 network operating system.

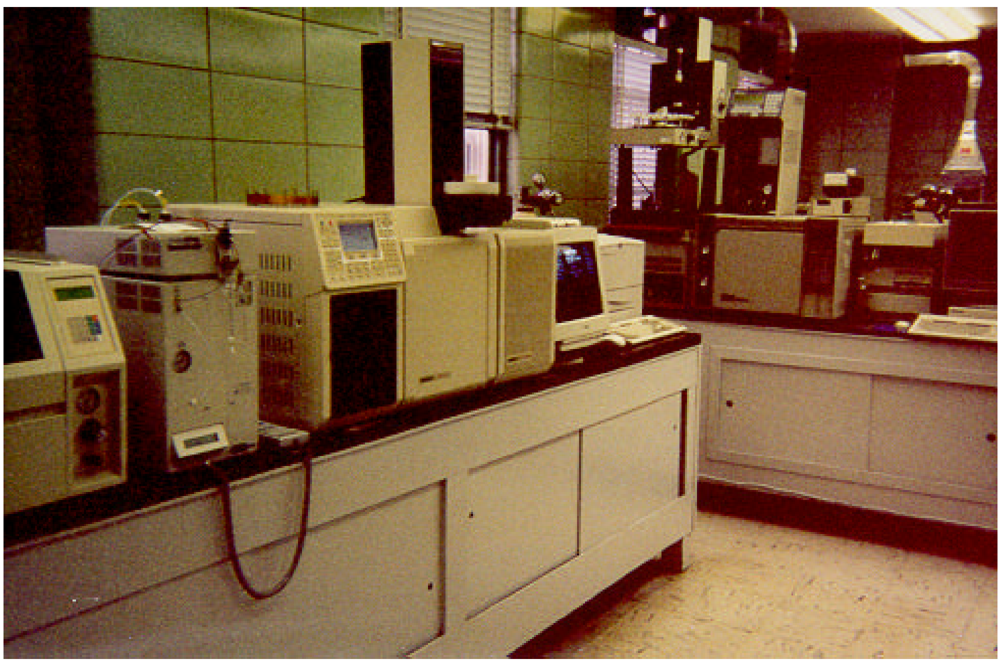
Software:

- SQL Server Licenses from Microsoft
- Arc Serve from Computer Associates
- Sample Master® Pro LIMS
- Delta-one Fieldworker software
- Diskeeper Server edition

ATL's project team consisted to three software engineers and a project manager. ATL engineers installed the server and required software. The engineers worked closely with the laboratory to ensure that there would be minimal impact on the day-to-day laboratory operations during the installation. The project manager was responsible for ensuring that third party software and hardware products were delivered on time and free of defects. Following the configuration of the server and installation of the software, ATL software engineers reviewed the custom reports that were required by the laboratory and also reviewed the requirements for integration with the WAD SCADA database.

Sample Master® Pro LIMS was implemented in phases, the first phase consisted of acquiring all the necessary hardware and software required for the project. Once the various components arrived, they were inspected and installed at the WAD laboratory. The focus of the first phase was installation of the server, configuration and installing Sample Master® Pro LIMS software. This phase also involved collecting output files from instruments that were to be integrated with the LIMS. and installing the required software for the data loggers, two handheld units that allow field workers the ability to collect field data and upload that data to Sample Master® Pro LIMS.

The focus of the second phase was instrument integration and installing and testing of the software to integrate the LIMS with the WAD SCADA database. The following instruments were interfaced with Sample Master® Pro LIMS: Agilent ICP-MS, Tekmar-Dohrman TOC, Varian Saturn GC-MS, Agilent GC-MS, Dionix IC.



The benefits of instrument integration include the following; a reduction in transcription errors, increase in automation, data accuracy and increased throughput. The cost savings alone justify the integration of instruments to Sample Master® Pro LIMS.

The last phase focused on training and final installation of the last two instrument parsers. In addition to training end-users, ATL software engineers also trained the LIMS database administrator (dba). End-users were trained with user manuals that went through each module with step by step instructions and the administrator guide was used to train the dba.

Conclusions

The selection and installation of Sample Master® Pro LIMS has resulted in many data management and automation improvements in the laboratory. There is now a full chain of custody, audit trail and many quality control enhancements that assist the laboratory in their data management challenges. By limiting users to tests and methods on pull-down lists, instrument integration, and requesting that users log onto the system with user name and password, there is a higher degree of data integrity.

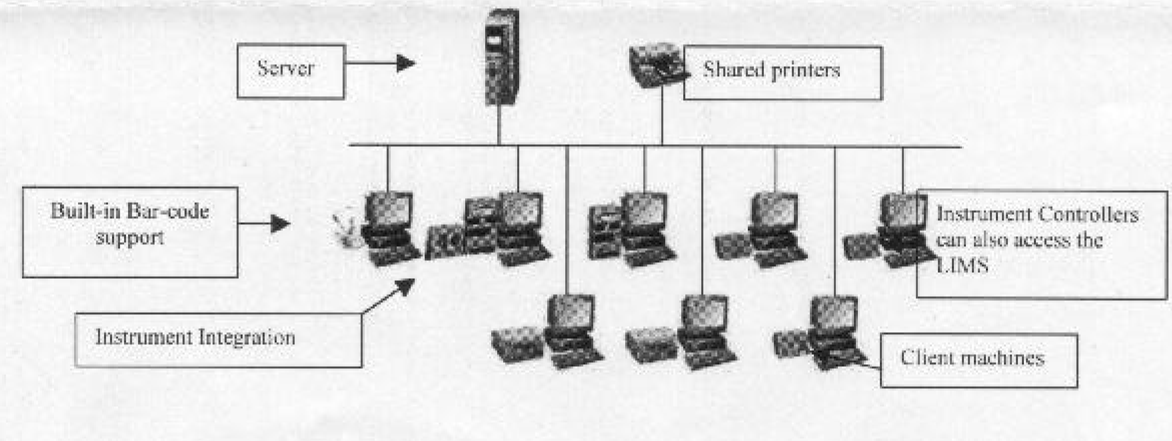


Figure 3. The schematic depicts a client/server configuration of Sample Master Pro LIMS.

Instrument integration has significantly reduced the amount of time analysts devote to data entry. Prior to the LIMS, entry of VOC data (60+ parameters per sample) would take hours. Since instrument integration, data entry has been reduced to review of the data and importing it into the LIMS – a process completed in minutes. Transcription errors are eliminated. Analyst time once spent entering data can now be devoted to other tasks.

Prior to implementation of the LIMS, reports were generated on a weekly to semimonthly basis. Sample Master® Pro LIMS has been setup for automatic report generation so that reports are automatically printed once sample results have been approved by the laboratory manager. The turnaround time of reports has been greatly decreased.

Implementation of the LIMS has greatly increased the efficiency of the laboratory. Data is readily available to view and approve. Instrument integration has reduced data entry time and transcription errors. Data loggers have reduced the amount of time required to log in samples to the laboratory. Quality control records are readily available for review and generation of control charts, once a laborious process, can now be completed in minutes.

J. Status Monitoring

	REF.	COMPLY	DO NOT COMPLY	COMPLY WITH MOD.
Provide methods for monitoring sample status throughout the sample life-cycle log-in:	**J1**			
Automatic update of sample status based on events or transactions	**J1**			
Provide a method to monitor test and analysis data	**J2**			
Provide codes to monitor sample status for the following conditions:				
- Sample received by the laboratory	**J3**			
- Samples expected or logged but not received	**J3**			
- Sample has tests assigned that are in progress	**J3**			
- All assigned tests are completed	**J3**			
- Sample results have been reviewed and verified	**J3**			
- A retest has been ordered	**J3**			
- Broken sample container	**J3**			
- Custom status codes defined by the laboratory	**J3**			
Provide codes to monitor test and analysis status for the following conditions:				
- Test is complete	**J4**			
- Test results have failed quality control	**J4**			
- Test results exceed specified limits	**J4**			
- Test results have associated text or limits violations	**J4**			
- Test is assigned to a bench sheet and is in progress	**J4**			
- Test results have been reviewed	**J4**			
- A re-test has been ordered for the same sample and test	**J4**			
Provide a means for informing when a sample may be disposed of	**J5**			
Allow customers read only access to their data via the internet or customer call up	**J6**			
Customers can easily view their current and historical results	**J6**			

Figure 1. Illustrates a sampling of some of the questions taken from the Request for Proposal created by the Washington Aqueduct Laboratory.

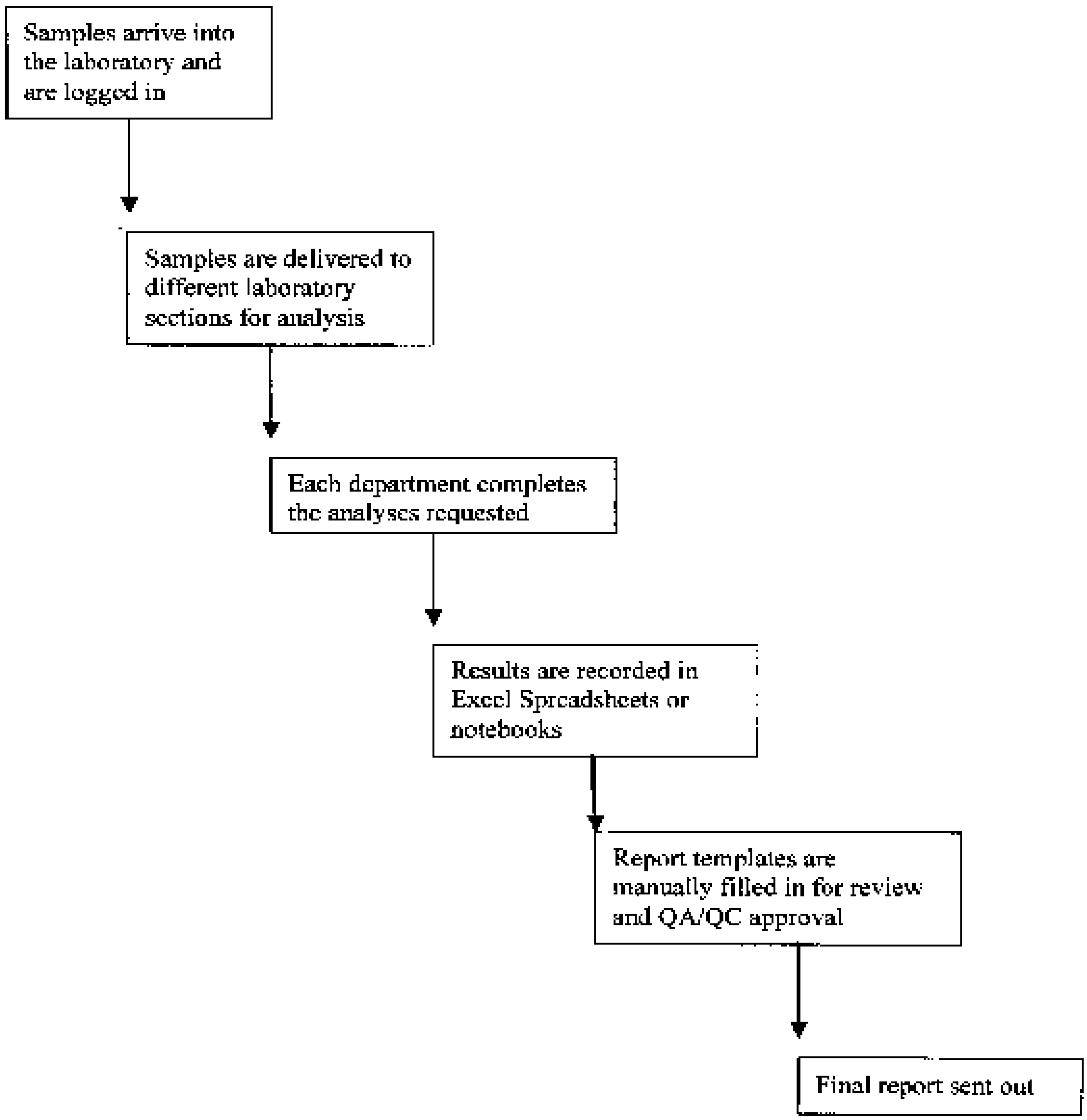


Figure 2. Schematic sample flow through the Washington Aqueduct Laboratory prior to the installation of Sample Master Pro Laboratory Information Management System.

AN INNOVATIVE APPROACH IN DEFINING AND PRODUCING LABORATORY ELECTRONIC DATA DELIVERABLES

Michael S. Johnson, Analytical Operations/Data Quality Center (AOC),
U.S. Environmental Protection Agency, Office of Emergency and Remedial Response

Abstract — The Contract Laboratory Program (CLP), managed by USEPA's Analytical Operations/Data Quality Center (AOC), has been receiving and utilizing laboratory Electronic Data Deliverables (EDDs) for over 14 years. These deliverables are utilized for verification of contractual and technical compliance, data assessment as part of the data validation process, monitoring analytical method performance and populating databases for statistical analysis, Geographic Information Systems (GIS) or other support and monitoring activities. The EDDs have been rigid, contract-specific formats, tailored to specific CLP reporting requirements. The CLP has been evolving over the last several years to become more flexible and to focus on customers' changing needs for method flexibility and utilizing alternative methods. To accommodate this program flexibility requirement, AOC developed the framework and the tools to introduce and utilize a new type of EDD, the Superfund Electronic Data Deliverable (SEDD).

SEDD utilizes Extensible Markup Language (XML) technology and the Internet to provide the basis for a laboratory EDD that is flexible, yet provides uniformity for EDDs across various methods and levels of reporting requirements. AOC provides an Internet-based tool set that can be utilized by laboratories to generate and deliver a requested EDD from the laboratory's database. Reporting requirements for specific methods or projects can be defined in a Document Type Definition (DTD) that is downloadable by the laboratory. AOC has also been collaborating with the U.S. Army Corps of Engineers (USACE) to utilize a uniform set of data element definitions and to define multiple stages of data deliverables that meet the needs of differing data requesters. Both AOC and USACE are piloting the new data reporting technology and toolset with analytical laboratories.

Introduction

The Analytical Operations/Data Quality Center (AOC) manages the environmental analytical data for the Contract Laboratory Program (CLP) in support of USEPA's Superfund program. CLP provides data through its routine chemical analytical services, and has implemented supporting services to ensure that known quality data is provided to CLP users. Since the CLP's inception in 1980, more than 1,850,000 samples from over 10,000 sites have been analyzed by over 430 laboratories. The CLP has been utilizing Electronic Data Deliverables (EDDs) in addition to hardcopy reports for verifying contractual and technical compliance to specified analytical methodologies and Q/C requirements. These EDDs are then available for performing data assessment, monitoring analytical method performance and populating databases for statistical analysis, Geographic Information Systems (GIS) or other decision support and monitoring activities. Currently, AOC is developing the Superfund Electronic Data Deliverable (SEDD) system to enhance CLP's data exchange needs in order to support multiple users' electronic data requirements by taking advantage of Internet-based data exchange standards.

Background

The use of EDDs within the CLP is vital for maintaining the integrity and availability of high quality data in large volumes, and has the following advantages:

- Facilitates system-to-system data transmission,
- Minimizes human intervention,
- Speeds up the processing of data,
- Reduces error, and
- Facilitates information transfer, storage and utilization.

In 1988 AOC introduced the "Format A" EDD to receive electronic data. The data organization of "Format A" was very similar to the hardcopy forms, essentially containing header information followed by detailed information for results. AOC then proceeded to enhance the capabilities of the EDDs by introducing "Format B" in 1989. Because of limited gain in capabilities, "Format B" was eventually replaced in 1991 by Agency Standard Format (ASF). The ASF, still in use today, to a great extent successfully captured the analytical results along with quality control information including instrument tuning and calibration data. The information was captured using the relative position of the data items in the file structure to establish relationships within the data groups and within analytical runs. The USEPA mainframe systems, such as Contract Compliance Screening (CCS), were utilized for verification of contractual and technical compliance of the data delivered in ASF files. Some instrument data processing software vendors and Laboratory Information Management Systems (LIMS) supported the creation of ASF files and CLP hardcopy forms within the laboratory.

Need for Flexible EDD

Although these EDDs have proven to be functional and achieved support from participating laboratories and their software vendors, they were soon facing constraints and limitations due to the rigid format. The current EDDs require strict adherence to structure and format in order to be effective. The resource impacts from changes were severe even when new analytical and reporting requirements were minimal. Adding or removing data elements, introducing Quality Control Samples, or Data Quality/Validation criteria windows all required large investments of time and money by USEPA and the laboratories. The current EDDs are dependent on software vendors' development time lines and software updates. They are not easily adaptable to the changing analytical needs of USEPA and other customers of analytical data. These limitations severely impacted CLP's evolution to serve its customers' changing needs.

AOC soon realized the following attributes would be necessary for the next generation of EDDs:

- Increased flexibility and compatibility with open industry standards,
- Reduced complexity,

- Reduced dependence on programmers to empower users, and
- A generic information format that can accommodate all environmental analytical data.

The SEDD Initiative

In its quest for a flexible EDD solution, AOC evaluated several EDDs including the Agency Standard Specifications, other EDDs used by USEPA offices and Federal agencies, and Electronic Data Interchange (EDI) standards such as ANSI X12 and UN/EDIFACT. Although none of the EDDs adequately addressed the changing needs of the CLP, information and requirements were extracted from these specifications pertinent to a Superfund EDD. AOC decided that SEDD would be an open transmission standard taking advantage of the benefits of Extensible Markup Language (XML) instead of a traditional EDD. Recommended by the World Wide Web Consortium (W3C), XML was selected as a key to SEDD's implementation because it is license-free, platform-independent, encapsulates structured data in text files and is well supported by freely available third party tools. The SEDD system has been deployed as a Web-based data-driven application. Innovative technologies were applied to the development of SEDD which allow the following key featured benefits:

- The SEDD system interfaces seamlessly with the legacy mainframe data processing systems, saving USEPA the cost of developing new systems that process the XML data. Additionally it will streamline data assessment activities by reducing processing time and increasing reported analytical quality and results information submitted by the laboratories.

- The delivery of industry-standard XML files by the SEDD system enables the chemists/data evaluators and data users to browse and review original laboratory EDD deliverables conveniently with widely available XML editing and reporting tools.

- The SEDD system provides a flexible deliverable format and tools to accommodate changes without the additional cost and time previously required with the rigid ASF. The system's flexibility allows CLP to expand its capabilities by accommodating changes in existing Routine Analytical Service (RAS) analytical methods and utilizing new and additional non-RAS methods.

- The SEDD system reduces the burden on laboratories to create and format EDD deliverables. It also allows laboratory personnel to focus more on data generation and data quality, and less on producing EDDs that conform to a multitude of specified data structures and formats.

How SEDD Works

The SEDD system supports multiple data deliverable requirements by maintaining Document Type Definitions (DTD). Each DTD specifies data requirements of an XML deliverable at the Web server accessible to laboratories with a standard Web browser. The browser hosts a user friendly java applet interface, allowing the laboratory user to browse the DTDs for the specific data reporting requirements specified for a client's deliverable. The specifications are available for download to the local laboratory workstation. The downloaded information, known as a Data Element Map (DEM) file, is a representation of the DTD requirements. This information can be viewed within SEDD as a tree-like hierarchical structure of nodes and elements, defining the XML tag names and the data node relationships. SEDD allows users to map DTD requirements to their database.

The SEDD interface also accesses tables and fields from the ODBC-compliant laboratory data source and provides a query builder, which allows the user to select table names and field names through pick lists. Mapping the lab's data source to the EDD requirements is accomplished by building SQL statements through a simple interface. The mapped configuration is saved in the DEM file, which can be used repeatedly to generate specific deliverables as XML files from the laboratory data source. Once a file is generated, it is then validated against the selected DTD to ensure that the XML file is complete and valid. The SEDD transmission utility sends XML file via FTP to the SEDD server for data verification and validation.

The use of the SEDD tool to generate and validate these XML data files is very convenient and offers a 'turn-key' solution for the reporting of this data. However, most present-day laboratories may not store all reported data in a single or multiple databases. Some of the data is generated only by report generators or reported manually to customers. Some laboratories still have very limited automated data handling capabilities. The use of the SEDD tool to deliver data in the XML format is not required. The laboratories could independently generate these data files. The laboratories would be free to choose the approach that best fit their data generation capabilities. The required XML files could be directly generated from LIMS or generated by software provided by independent private sector vendors. These files could then be validated against the same DTDs as used by the SEDD tool and delivered to the client.

AOC and USACE

AOC has been collaborating with the U.S. Army Corps of Engineers (USACE) to utilize a uniform set of data element definitions and to define multiple stages of data deliverables that meet the needs of differing data requesters. AOC and USACE are jointly proposing three stages of data specifications defined as follows:

Stage 1. Contains the minimum number of analytical data elements to transmit results-only data to the end user.

Stage 2. Data content builds on Stage 1 by adding method and instrument quality control data (e.g., initial calibration, continuing calibrations, method QC limits, sample QC relationships).

Stage 3. Data content builds on the Stage 2 data set by adding additional measurement data to allow for independent recalculation of the reported results. Data in this stage will be similar in detail to the current CLP EDDs.

The three-staged approach was taken in order to provide uniform and scalable EDD requirements for the data providers as well as the data users. Proposed data elements and schema for reporting in each of the 3 Stages can be viewed on the AOC Web site at http://www.epa.gov/superfund/programs/clp/sedd.htm or at the USACE Web site at

http://www.environmental.usace.army.mil/info/technical/chem/chemtopics/chemedd/chemedd.html.

The data elements identified in each Stage represent the maximum reporting requirements for that Stage, however, specific programmatic EDDs (as defined in the DTD) may only require a subset of the specified data elements.

Utilizing the SEDD XML format would permit laboratories to support a particular reporting Stage by maintaining the required data in their LIMS or other database, or by capturing the data in a database view or utilizing commercial XML tools to extract the data from multiple sources. Once the three Stages of data specification are adopted, the environmental user community will benefit from having a single XML format that can support various EDD specifications. While few laboratories could currently support Stage 3 reporting requirements, most laboratories could now support Stage 1 reporting requirements and could move up to Stage 2 and 3 reporting as they update or implement new LIMS or databases. Also, different programs requiring Stage 1 or 2 data could implement their EDDs quickly utilizing the SEDD XML specifications.

Both AOC and USACE are piloting the new data reporting technology and toolset with analytical laboratories. AOC has also been working with the Office of Environmental Information (OEI) to utilize the SEDD tool set for laboratory reporting in other programs and for reporting other types of data.

Conclusion

SEDD's use of XML provides flexibility and format independence for all data reporting needs. DTDs are used to specify data requirements including data groups, data elements and their relationships. Each deliverable's data requirements are represented by a DTD on the SEDD Application Server giving SEDD the ability to support multiple users' electronic data requirements. The SEDD system easily accommodates future changes in requirements with minimal modification to existing systems through modifications of DTDs.

The XML output file is independent of proprietary data systems. A variety of parsers are available for viewing, editing, or programmatically processing these files to interface with different database systems.

SEDD's innovative XML approach will substantially contribute to the enhancement of analytical data quality by minimizing errors inherent in the reformatting and restructuring of data to comply with a multitude of reporting formats and will permit the use of common tool sets for data verification, validation and processing. The SEDD system can be an integral part of any Data Management System providing data exchange and inherently improves data quality.

NELAC QUALITY SYSTEMS:
THE INTEGRATION OF ISO/IEC 17025 AND PBMS

Scott D. Siders, Division of Laboratories, Illinois Environmental Protection Agency

Abstract - Within the past year the National Environmental Laboratory Accreditation Conference (NELAC) Quality Systems Committee has been working on a major restructuring of the quality systems standards to integrate the ISO/IEC 17025 international standard and performance-based measurement system (PBMS) concepts (i.e., additional flexibility) into the present standards. This paper will provide the rational for that effort and will give an update on the status of the Committee's activities in this and other key areas. Further, the paper will provide an overview of the present draft language, that relates to ISO/IEC 17025 and PBMS, for the NELAC Quality Systems chapter.

INTRODUCTION

The adopted June 29, 2000, NELAC Quality Systems standards (i.e., NELAC Chapter Five) are based on ISO/IEC Guide 25. NELAC has also stated its commitment to the use of Performance-Based Measurement Systems (PBMS) in environmental testing and toward providing a foundation for PBMS implementation in the standards. Hence, with the advent of ISO/IEC 17025 as the replacement for ISO/IEC Guide 25 and the Environmental Laboratory Advisory Board's (ELAB) PBMS Straw Model (presented at NELAC VIi) the NELAC Quality Systems Committee has begun efforts to develop proposed language for NELAC Chapter 5 that would integrate both ISO/IEC 17025 and the PBMS Straw Model concepts/elements into the standards. Obviously, the NELAC Quality Systems Committee initiation of this effort was done with the knowledge and support of both the NELAC Board of Directors and ELAB.

The primary goal of this effort is to improve overall quality of compliance data via the NELAC quality system standards. The Committee views the incorporation of the superior ISO/IEC 17025 international standard as its base and further utilization of a PBMS approach for performing environmental analyses under NELAC as a means to do just that: improve data quality. Additionally, many NELAC stakeholders view this integration effort as a means to bring about some positive and needed improvements in the current NELAC Chapter 5 language.

CURRENT ACTIVITIES AND DIRECTION

During NELAC VIi (November 2000) the NELAC Quality Systems Committee discussed its ISO/IEC 17025 integration efforts and also formed a PBMS Subcommittee to address the PBMS Straw Model. The NELAC Quality Systems Committee's ISO/IEC 17025 integration efforts were essentially delayed between NELAC VI and NELAC VIi due to ongoing ISO/IEC 17025 copyright and copyright licencing fee issues that NELAP had with ANSI. Those issues are still being considered by the NELAC Board of Directors and have had an impact on the direction the Quality Systems Committee has taken. Essentially both the above NELAC Quality Systems Committee efforts got underway only after NELAC VIi.

The NELAC Quality Systems Committee has as part of its ISO/IEC integration effort initially developed a spreadsheet that contrasts ISO/IEC 17025, NELAC Chapter 5 and ISO/IEC Guide 25 elements. This tool provided direction on the Committee's next steps. The Committee then identified the current ISO/IEC Guide 25 language in NELAC Chapter 5 for possible removal. The Committee has also inserted the present Chapter 5 language under the appropriate/corresponding ISO/IEC 17025 section since the ISO/IEC 17025 language will provide the framework for any revised Chapter 5. Lastly, due to the ANSI copyright issue, the Committee was also directed to be ready to provide a version of NELAC Chapter 5 that would only cite ISO/IEC 17025 by reference.

At present the Committee is working on drafting a revised NELAC Chapter 5 version that would have ISO/IEC 17025 sections as the main framework (yet structured as to be able to cite these sections by reference only if needed) with current and revised NELAC Chapter 5 language (either minus the old ISO/IEC Guide 25 language or with the ISO/IEC Guide 25 language highlighted) inserted were appropriate. Further, this revised NELAC Chapter 5 version would have inserted in it the revised sections of NELAC Chapter 5 that the PBMS Subcommittee is working on. The goal was initially to have this document ready for proposal at NELAC VII (May 22-25, 2001), but the extent and depth of the undertaking did not allow us to make the imposed March 19, 2001-deadline for Committee's to submit final proposed language to the NELAP Director.

ELAB's PBMS Straw Model which was heavily influenced by ISO/IEC 17025's Section 5.4 as it relates to how laboratories should implement and use laboratory methods brought two key concepts to the table. The two most significant concepts that have influenced the PBMS Subcommittee's efforts are:

- Method Selection; and

- Method Validation.

The PBMS Subcommittee identified NELAC Chapter 5's sections 5.10 (Test Methods and Standard Operating Procedures), 5.9.4 (Calibration), and Appendix C (Demonstration of Capability) as important areas to revise to address the PBMS Straw Model concepts/elements. To date the PBMS Subcommittee has essentially completely rewritten or plans or rewriting Chapter 5 section 5.10 and Appendix C. Significant revisions are being drafted for sections 5.9.4 (Calibration) and a few changes in section 5.5.4 (Quality Manual) and elsewhere in the main body of Chapter 5.

Again, the NELAC Quality Systems Committee's ISO/IEC 17025 integration effort and the PBMS Subcommittee's efforts will be fused into a single discussion document (not to be put for a vote) that will be brought to NELAC VII in Salt Lake City for public consideration and discussion during the NELAC Quality Systems session.

However, the NELAC Quality Systems Committee will be bringing to NELAC VII as proposed language and putting up for a vote the Committee's rewrite of Appendices D.1 (Chemical Testing) and D.3 (Microbiology Testing). The D.3 proposed language was discussed at NELAC VIi and the D.1 proposed language is based on the ELAB's May 2000 proposed revisions to D.1. The ELAB's May

2000 proposed changes to D.1 were publically discussed and widely supported at NELAC VIi as part of the NELAC Quality Systems Session.

LANGUAGE THAT RELATES TO ISO/IEC 17025 & PBMS STRAW MODEL

Obviously, with possibly bringing the entire ISO/IEC 17025 international standard into NELAC Chapter 5 there would be new language that would represent some changes from the current ISO/IEC Guide 25 based Chapter 5. While ISO/IEC 17025 has more emphasis/detail in the technical requirements there appears to be greater flexibility within ISO/IEC 17025.

New ideas in the technical requirements in ISO/IEC 17025 that will likely be brought into NELAC Chapter 5 are:

3. reference to "needs" of the clients;
4. requirement for sampling plan when sampling done by laboratory;
5. method validation;
6. calculation/estimation of measurement uncertainty for testing laboratories; and
7. provisions for inclusion of interpretations and opinions in test reports.

ISO/IEC 17025's management requirements also introduce some new aspects as compared to ISO/IEC Guide 25. Some new aspects found are:

1. identification of potential conflicts of interest;
2. more detailed requirements for quality policy statement;
3. specific requirements for control, review, and approval, issue and amendment of documents;
4. major changes in the Requests, Tenders, and Contracts section (e.g., identify customer needs, ensure capability to meet needs, dealing with changes and deviations);
5. incorporate ISO 9001 requirements in simplified form for purchasing;
6. specific procedures for dealing with non-conforming work/results and the need for corrective action;
7. specific procedures for cause analysis, selection and implementation of corrective action, subsequent monitoring and follow-up audits;
8. preventive action requirements deals with potential problems and quality improvement process;
9. records requirements now consistent with ISO 9001; and
10. specific guidance on matter to be considered during management reviews.

Again, while the above are generally new aspects that will need to be considered, the overall ISO/IEC 17025 standard is much less prescriptive and introduces greater flexibility on how to accomplish the requirements. Some of the above items like corrective action, management reviews, records and reporting are already addressed in detail in NELAC Chapter 5. Actually the present NELAC Chapter 5 utilized some draft ISO/IEC 17025 language for the management reviews and corrective actions sections.

It is this inherent flexibility written into ISO/IEC 17025, especially in relation to method validation, that the PBMS Subcommittee hoped to capture in its below draft 5.10 language for Chapter 5. Again the PBMS Straw Model elements/concepts are also based upon section 5.4 of the ISO/IEC 17025 standard. The following in the draft language for Chapter 5 section 5.10 that has been developed as of February 28, 2001.

Please Note: This language is still draft and undergoing internal review and comment by other PBMS Subcommittee members. It has not been reviewed by the NELAC Quality Systems Committee. It is only being shared as part of this paper as only a means to communicate the general direction the PBMS Subcommittee is heading with its extensive rewrite of section 5.10. The PBMS Subcommittee has just started work on revisions to the current Appendix C in NELAC Chapter 5. The revised 5.10 and Appendix C will be the keys to implementing ISO/IEC 17025 section 5.4 with the NELAC Quality Systems standards.

Here is the February 28, 2001 draft section 5.10 as drafted by the PBMS Subcommittee:

5.10.1 Methods Documentation

a) The laboratory shall have documented SOPs on the use and operation of all equipment involved in the measurement, on the handling and preparation of samples, and on calibration and/or testing, where the absence of such instructions could jeopardize the reliability of calibrations or tests

2. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

5.10.2 Laboratory Methods Manual and Standard Operating Procedures (SOPs)

The laboratory shall maintain a methods manual. The methods manual shall contain the laboratory's standard operating procedures (SOPs). The SOPs shall accurately reflect all phases of current laboratory activities such as sample receipt, sample storage, sample analysis, assessing data integrity, corrective actions, handling customer complaints, all test methods, and data and record storage

a) An SOP may be an equipment manual provided by a manufacturer, or an internally written document so long as the SOP is adequately detailed to permit someone other than the analyst to reproduce the procedures that had been used to produce a given result.

b) The test method SOPs may be copies of published methods as long as any changes or selected options in the methods are documented and included in the SOPs (see 5.10.1.2). Reference test methods that contain sufficient and concise information on how to perform the tests do not need to be supplemented or rewritten as internal procedures if these methods are written in a way that they can be used as published by the laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

c) Copies of all SOPs shall be accessible to all personnel.

d) SOPs shall be organized in a manner such that they are easily accessible to an auditor.

e) Each SOP shall clearly indicate its effective date, its revision number and shall bear the signature(s) of the approving authority.

f) Each test method SOP shall give or reference the following information, where applicable:

1.0 Scope and Application
2.0 Summary of Method
3.0 Definitions
4.0 Interferences
5.0 Safety
6.0 Equipment and Supplies
7.0 Reagents and Standards
8.0 Sample Collection, Preservation, and Storage
9.0 Quality Control
10.0 Calibration and Standardization
11.0 Procedure
12.0 Data Analysis and Calculations
13.0 Method Performance
14.0 Pollution Prevention
15.0 Waste Management
16.0 References
17.0 Tables, Diagrams, Flowcharts, and Validation Data

5.10.3 Use of Test Methods

All measurements made which operating as a NELAC accredited laboratory, must have an adequate demonstration that the measurement system provided data consistent with its intended use. The laboratory shall ensure the quality of results provided to clients by implementing a system to document the quality of the laboratory’s analytical results. This demonstration consists of three activities, 1) an initial determination that the measurement system is capable of providing data of the quality needed to meet client and/or regulatory requirements (see 5.10.3.2); 2) an acceptable instrument calibration and verification that the system has remained calibrated during the period that it was used for analysis, and 3) documentation of the quality of any data that was obtained. The specific activities performed for this demonstration are defined below and in Appendices C and D.

5.10.3.1 Method Selection

The laboratory shall utilize methods within its scope (including sample collection, sample handling, transport and storage, sample preparation and sample analysis) which are appropriate and applicable to client needs (i.e., to meet regulatory or other requirements specified by the client). These requirements may specify that a particular method, or group of methods be employed for a given project or program; or that specific data or measurement quality objectives be achieved; or both. I.e., data or measurement quality objectives specified by the client or required of the client to demonstrate regulatory compliance define the boundary conditions of the method selection process.

1. When the use of a particular test method is mandated by a regulatory agency or is requested by a client, only that method shall be used. Deviations from a reference test method shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client and/or regulatory agency. The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.

2. In the event that a specific method is not required by a regulation or a client, the laboratory may select another, alternative methods, provided that it will yield data of sufficient quality to meet client requirements. When use of a particular method is not required by a client, the laboratory should preferentially employ methods published by consensus standards organizations, government agencies such as USEPA, reputable technical organizations, or those that are published in peer reviewed journals. When using such a method, the laboratory shall ensure that it uses the latest valid edition of a method unless it is not appropriate or possible to do so. When necessary, the method shall be supplemented with additional details to ensure consistent application.

3. A laboratory-developed methods or a method adopted by the laboratory may also be used if validated for the intended use. The client shall be informed as to the method chosen. If the selected method is changed, the validation shall be repeated

4. Client approval must be obtained prior to implementation. Modifications must be documented in and referenced in reports to the client.

5.10.3.2 Method Validation

The laboratory must routinely perform and document the quality of the measurement system relative to the materials being tested. This activity is termed "method validation." The thoroughness and robustness of the validation depends on what is already known about the performance of the method on the analyte-matrix combination of concern over the concentration range of interest. Properties of the measurement system to be validated include bias, precision, sensitivity, and selectivity. The measurement system includes the analyst (operator) or work cell and method.

Essential elements of method validation include measures to determine positive or negative bias, to assess variability and/or repeatability, to determine sensitivity, range, and response, to ensure selectivity of the test method for its intended purpose, and to ensure constant and consistent test conditions where required by the system.

The laboratory shall validate each method for its intended use according to Appendix C. The laboratory shall record the results of the validation, the protocol used for the validation, and the basis for the stated measurement system performance. When changes are made in a validated method, the influence of such changes shall be documented and, if appropriate, a new validation shall be carried out.

The thoroughness of any method validation is always a balance between costs, technical possibilities, available time, and the consequences of error. There are many cases in which the range and uncertainty of the values (e. g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be approximated. However, so long as the level of approximation is commensurate with the needs of the client, such tradeoffs are acceptable.

5.10.3.3 Quality Control Procedures

In addition to the requirement for validation, the following general quality control procedures shall apply, wherever applicable. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., chemical, whole effluent toxicity, microbiological, radiological, air) and are further described in Appendix D. The standards for any given test type shall assure that the applicable principles are addressed:

1. The laboratory shall have quality control procedures in place to monitor the performance of the measurement system on an on-going basis, including:

1. procedures to ensure that the measurement system is free of laboratory induced interferences;

2. procedures to identify if and when analytical instruments are in an out-of-control condition;

3) procedures to verify continuing analyst proficiency;

4) procedures to ensure the suitability of reagents and standards; and

5. measures such as temperature, humidity, light, or specific instrumental conditions, to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method.

b) All quality control measures shall be assessed and evaluated on an on-going basis, and quality control acceptance criteria shall be used to determine the usability of the data. (See Appendix D.)

3. The laboratory shall have procedures for the development of accept/reject criteria where no method or regulatory criteria exist. (See 5.11.2, Sample Acceptance Policy.)

The essential quality control measures for testing are found in Appendix D of this Chapter.

As you can tell the yet to be revised Appendix C will be integral in regards to the method validation step. The PBMS Subcommittee draft Appendix C will hopefully be ready to include into any discussion document taken to NELAC VII. I want to reiterate that the above is only an internal draft still subject to change and does not represent proposed language up for vote at NELAC VII. I hope sharing this draft language helps foster discussion and disseminates information on the NELAC Quality System Committee's present efforts.

CONCLUSION

The advent of ISO/IEC 17025 and the PBMS Straw Model are generating considerable discussion and efforts within the NELAC Quality Systems Committee and its PBMS Subcommittee. This paper is an attempt to capture the direction the Committee is heading to address these items as they relate to quality systems. It is the hope of the NELAC Quality Systems Committee to present a complete discussion document at NELAC VII for discussion-purposes-only that will highlight possible proposed language to be presented at the next NELAC Interim Meeting (NELAC VIIi). At NELAC VII the Quality Systems Committee and the PBMS Subcommittee will welcome your feedback on the direction they are taking. The USEPA, DOD, other federal agencies, States and the private sector are significant stakeholders in this process and need to participate fully in NELAC to ensure the quality systems standards developed do indeed improve overall data quality.

OBSERVATIONS OF LABORATORY CHANGES AS A RESULT OF THE NELAC STANDARDS

Marlene O. Moore, Advanced Systems, Inc.

Abstract — As laboratories implement and adopt the NELAC standards, uniformity of records, quality control, standards/reagent labeling and SOP contents have been observed. Although a lot of criticism about consistency of the assessments is presented at NELAC and other meeting, there are a number of areas where consistency is better defined and implemented. This consistency provides data users with uniform documented information that was not previously available from laboratories. This presentation includes the observations made by one independent assessor relating to laboratory operational consistency as a result of NELAC. In addition the top laboratory findings from August 1999 to June 2000 as compiled from the eleven accrediting authorities will be included in the presentation.

During the last year of assessments, a number of items found in laboratories across the country have become more uniform and consistent. This consistency is a result of the implementation of the NELAC standards by laboratories. As laboratories implement and adopt the NELAC standards, uniformity of records, quality control, standards/reagent labeling and SOP contents have been observed. Although a lot of criticism about consistency of the assessments is presented at NELAC and other meetings, there are a number of areas where consistency is better defined and implemented.

NELAC continues to struggle to ensure assessment consistency as accrediting authorities conduct the on-site assessment. Laboratories are implementing the standard and uniformity is evident.

Before the implementation of NELAC training records were often found in various places and contained a variety of information. In some laboratories no records were found at all. NELAC changed this to require the laboratory director and QA manager to be responsible for certifying personnel as trained in the laboratory. NELAC provides a form (Appendix C) that laboratories have adopted and is resulting in more consistent records. In addition personnel are more familiar with the methods cited on the form and are familiar with performance measures required to maintain the status of a trained analyst.

Test records now contain the same minimum number and types of quality control samples. Records before NELAC did not always include a method blank and laboratory control sample. Since many reference methods do not indicate these samples in the specific method, laboratories did not perform these samples. The reference method often included the requirement for a blank and control sample, but it was located in another section of the reference document.

With NELAC the chemistry and microbiology Appendix clearly indicate the need for these quality control samples. This allows data review to include these parameters on a more consistent basis. In addition NELAC requires a quality control sample at the reporting limit which ensures that measurements reported to clients are bracketed with standards. In many reference methods this is not clearly stated and often results are reported for values without a standard to verify the measurement is possible.

Besides record improvement, a consistent method of labeling standards and reagents is found. NELAC requires the labeling of these materials to indicate the expiration date. The preparation date, open date, receipt dates are not required on the label. In the past, the labeling was dependent on the program, the auditors and state. It was not uniformly defined and personnel often were cited for not having a receipt date or open date. NELAC requires the necessary information on the label that is the expiration date. Standards and reagent logbooks include all information, but the label is only required to have the information needed by the user. The label must indicate when the material expires. The records of the laboratory allow traceability of preparation and lot number of reagents and standards. The containers are found in the laboratory to be more uniformly labeled not only within the laboratory, but also between laboratories.

Many laboratories have spent significant amount of time and dollars to rewrite the laboratory procedures to meet the content requirements specified in NELAC. As a result of this, laboratories SOPs are more complete and are following a uniform standard for content. These SOPs are more reflective of the laboratory operations and document modifications from the EPA methods. In the past, assessors had to compare the laboratory method with the reference method. Now many laboratories are identifying the modifications in order to indicate that these modifications do not impact the data quality. These modifications are often justified in the SOP and demonstration of equivalency cited.

Although consistency is underway, many parts of the standard are subject to interpretation. These areas are presented to NELAC and improvements are underway. In the meantime findings among the accrediting authorities are found to be consistent. Although outliers may exist in any one state or one assessor, the assessments are finding the same types of deficiencies.

The NELAC standard from 1999 requires many new and additional requirements that laboratories have not routinely implemented. The number after the citation is the NELAC 1999 standard reference. The entire wording from the standard is summarized here.

The top ten findings from August 1999 to June 2000 as compiled from the eleven accrediting authorities are:

1. Laboratory shall have processes to ensure that its personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work (5.4.2.b)
2. Nominate deputies in case of the absence of the technical director(s) and/or quality assurance officer (5.4.2.h)
3. Have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights (5.4.2.i)
4. Procedures for protecting confidentiality (including national security concerns), and proprietary rights (5.5.2.r)
5. All audit and review findings and any corrective actions that arise from them shall be documented.

6. The laboratory management shall ensure that these actions are discharged within the agreed time frame. (5.5.3.3)
7. The laboratory shall use appropriate test methods and procedures for all tests and related activities... The method and procedures shall be consistent with the accuracy required and with any standard specifications... (5.10.2.a)
8. Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that: all requirements are met . . . (5.10.6. b - e)
9. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. (5.1.b)
10. Method Blanks - performed at a frequency of 1 / batch / matrix type / prep. The source of contamination must be investigated, corrected …. Any sample associated with the contaminated blank shall be reprocessed or the results qualified. (D.1.1.a.1)

Additional findings that are frequently reported from the accrediting authorities include:

Organization

- The laboratory must specify and document the responsibility, authority, and interrelation of all personnel …
  - in job descriptions for all positions (5.4.2.d)in
- The QA officer
  - arranges for or conducts internal audits on the entire technical operation annually
  - notifies lab management of deficiencies in the quality system
  - monitors corrective action (5.4.2.g.6)

System - Findings

- Quality Manual incomplete (5.5.2)
- Objectives not documented (5.5.2.a; 5.5.1.c)
- Records retention and document control procedures not available (5.5.2.d)
- Signatures QM missing (5.5.2.f)
- Procedures for measurement traceability not available (5.5.2.g)
- Review of new work not defined (5.5.2.i)
- Ethical training not documented (5.5.2.u)
- Management review not complete (5.5.3.2)
- Corrective actions not implemented (5.5.3.5)

Training - Findings

- Demonstration of Capability not documented (5.6.2 b, C-1, 5.10.2.1, D.1.3.a)
- Training not kept up to date (5.6.2.c)
- Proactive program for detection of improper actions (5.6.2 h)

Facilities & Equipment - Findings

- Recording & control of environmental conditions (5.7.1.c)
- Equipment records not complete (5.8.e)

Traceability - Findings

- Calibration and verification of equipment including balances, thermometers, standards (5.9.1)
- Maintenance records and service calls (5.9.4.1.a)
-

Methods - Findings

- Documented instructions (5.10.1.a)
- SOPs not available (5.10.1.1)
- Effective date not defined (5.10.1.1.e)
- Methods manual not available (5.10.1.2)
- Procedures for obtaining subsamples (5.10.3)
- Procedures for purchase, reception, and storage of consumable materials (5.10.5)

Sample Handling - Findings

- No system for uniquely identifying samples (5.11.1.a)
- Documentation of sample conditions not per reference method or program (5.11.3.a)

Records - Findings

- Records do not include all activities (5.12)
- Control of logbooks and records incomplete (5.12.2.d)

Report - Findings

- Reports contents not per standard (5.13.a)
- Subcontractors not identified on report (5.13.c)
- Amendments to reports not identified (5.13.d)

Subcontracting - Findings

- No records for subcontracting (5.14.c)

Chemistry - Findings

- Matrix spikes not performed at required frequency (D.1.1.b.2)
- MS duplicates and other duplicates not performed at required frequency (D.1.2)

- Calibration verification not performed at beginning and end of run (5.9.4.2.2.b)

Microbiology - Findings

- Duplicates and PT testing (D.3.2)
- Temperature devices calibrated annually and appropriate for use (D.3.8.c)

Reference:

National Environmental Laboratory Accreditation Conference Standard, , Chapter 1 to 5 with Appendices, July 1999, USEPA.

AARB PRESENTATION

Carol Madding, U.S. EPA

Abstract — The NELAC Accrediting Authority Review Board monitors NELAP to assure that EPA is following the NELAC standards, serves as a review board for accrediting authorities that have been denied NELAP recognition or have had such recognition revoked and conducts assessments of the NELAP process for recognizing Accrediting Authorities. In essence, the Board watches over NELAP to be certain it has a Quality System in place and that the Quality System is satisfactory and is being followed. The idea of the need for such a board and the responsibilities assigned to the Board developed over time and are still evolving. This presentation will discuss the evolution of the board, its responsibilities, what it can and cannot do, and recent activities. Major activities include development of processes to perform their functions, review of a possible revocation of an AA's recognition, and assessments of the NELAP Accrediting Authority Recognition Process.

WILL ANYONE EVER READ THE LAKE MICHIGAN MASS BALANCE QUALITY ASSURANCE REPORT?

Louis Blume, U.S. EPA, Great Lakes National Program Office
Judy Schofield, DynCorp I&ET, Inc.
Lynn Riddick, DynCorp I&ET, Inc.
Debra Piper, Grace Analytical Laboratories
Marcia Kuehl, Grace Analytical Laboratories

The Lake Michigan Mass Balance Study (LMMB Study) is a coordinated effort among state, federal, and academic scientists to monitor tributary and atmospheric pollutant loads, develop source inventories of toxic substances, and evaluate the fate and effects of these pollutants in Lake Michigan. By achieving LMMB Study goals, federal, state, and tribal agencies will be able to make more informed load reduction decisions. A key objective of the LMMB Study is to construct a mass budget and mass balance model for a limited group of contaminants that are present in Lake Michigan at concentrations that pose a risk to aquatic and terrestrial organisms within the ecosystem.

The LMMB is the most comprehensive study of its kind and involves one of our national treasures (Lake Michigan). Therefore, the community of primary and secondary users is likely to be both broad and diverse. Data users, environmental managers, and policy makers will use the study's mass balance model to make assessments and decisions regarding future environmental policy and regulations. Academic, environmental, and industry groups will likely use LMMB data to identify needs for further study or support arguments advancing their position with respect to environmental control or development in the Great Lakes region. The challenge we face as QA Managers is to ensure that such a large and diverse group of data users understands the strengths and weaknesses of the data they are using.

How do we respond to such a challenge? The Great Lakes National Program Office (GLNPO), which was responsible for managing the study, took a three-pronged approach by:

- Implementing a rigorous QA program during the data gathering phase
- Developing a relational database that would allow detailed statements of data quality to be carried with each and every result generated, and
- Documenting the quality of the data in a written QA report at the conclusion of the study.

The rigorous QA program was intended to control the quality of data as it was being generated. The point was to ensure a maximum amount of data would meet data quality objectives established for the study. The QA program prescribed minimum requirements to which all organizations collecting data were required to adhere. QA activities included QA program planning, establishing a QA workgroup, training, verification of all submitted data sets, implementing a standardized data reporting format, and QA project plan (QAPP) development. As a component of study QAPPs, principle investigators (PIs) were required to develop Measurement Quality Objectives (MQOs). These MQO's were designed to control various phases of the measurement process and to ensure that the total measurement uncertainty was within the ranges prescribed by study data quality objectives.

The database design was intended to ensure each data user understood the limitations of the individual results on which they were basing decisions. For example, results measured below the detection limit were reported in the database as requested by the modelers, but each of these results is flagged to indicate that the figures are below the detection limit so that the modelers and other data users understand the inherent limitation of such results. Documentation of data quality at the result level allows the broadest use of the data by secondary users because they can disregard or include flagged data according to their data quality needs.

The QA Report is intended to ensure that data users understand the overall quality of each data set. Instead of presenting data quality concerns at the result level (as does the database), the report presents data quality information by parameter and highlights data quality issues associated with estimating pollutants in various ecosystem compartments, such as variations in sensitivity. The report also includes statistical assessments of each data set in terms of six data quality attributes: sensitivity, precision, accuracy, representativeness, completeness, and comparability. In doing so, the QA report not only documents the overall quality system employed for the LMMB, it provides data users with a broad level understanding of data quality and an opportunity to focus on lessons learned, QA trends, and measurement areas in need of of further improvement. Will anyone read it?

EPA'S COASTAL 2000 MONITORING PROGRAM IN THE NORTHEAST U.S. - CONSISTENCY IN METHODS AND QUALITY ASSURANCE

Charles J. Strobel, Joseph A. LiVolsi, Jr., Donald S. Cobb,
John F. Paul, Gerald Pesch, and Walter Galloway
U.S. EPA - Atlantic Ecology Division, Narragansett, RI

Abstract: As part of EPA's national Coastal 2000 effort to estimate the ecological condition of our Nation's estuarine resources, sampling of the estuaries of the northeast United States (Delaware to Maine) began in the summer of 2000. Samples and data were collected to determine water quality, sediment quality, benthic community condition, and fish health. Unlike earlier EPA monitoring programs, Coastal 2000 enlisted the assistance of coastal states for data collection. In addition, the program attempted to include many of the currently existing estuarine monitoring programs. To ensure comparability of results, all states monitored a core suite of indicators using standardized collection methods under an EPA-approved Quality Assurance Plan. Components of the QA program included, meetings to formalize QA and sampling protocols, training of all field crews by EPA personnel, the voluntary use of EPA-provided field data sheets and data entry system, the voluntary use of bar codes for sample tracking, and routine field and laboratory QA audits conducted by EPA personnel. As a result of this significant QA effort, the program succeeded in both collecting high-quality, consistent data and transmitting this information to the Coastal 2000 central information management system. Further, steps taken to standardize collection methods used by individual states serve to increase the comparability of data among the states in the estuarine Northeast United States thereby improving the quality of their 305b (Clean Water Act) submissions.

THE QUALITY MANAGEMENT SYSTEM AS A TOOL FOR IMPROVING STAKEHOLDER CONFIDENCE

Denise K. MacMillan, Environmental Chemistry Branch,
Army Engineer Research and Development Center

Abstract: The Corps of Engineers works with local restoration advisory boards (RAB) to exchange information and develop plans for restoration of closed military bases for civilian re-use. Meetings of the RAB to discuss progress in environmental assessment and restoration of former defense sites can be contentious due to the complex technical nature of the information to be shared and the personal stake that the members of the community have in ensuring that contaminated areas are restored for safe use. A prime concern of community representatives is often the quality of the data used to make environmental decisions. Laboratory case narratives and data flags may suggest laboratory errors and low data quality to those without an understanding of the information's full meaning.

RAB members include representatives from local, state, and tribal governments, the Department of Defense, the Environmental Protection Agency, and the local community. The Corps of Engineers representatives usually include project technical and management personnel, but these individuals may not have sufficient expertise in the project quality assurance components and laboratory data quality procedures to completely satisfy community concerns about data quality. Communication of this information to the RAB by a quality assurance professional could serve to resolve some of the questions members have about the quality of acquired data and proper use of analytical results, and increase community trust that appropriate decisions are made regarding restoration. Details of the effectiveness of including a quality assurance professional in RAB discussions of laboratory data quality and project quality management will be provided.

The US Army Corps of Engineers uses a twelve-element quality assurance program to assure that the data acquired for site investigations, remediation, monitoring, and other environmental projects meet project-specific data quality objectives. The elements are comprehensive in scope and integrate quality assurance activities into the planning, sampling, analysis, data assessment, and data validation stages of a project. The primary elements are laboratory validation, technical document review, sampling handling quality assurance, split sample collection and analysis, data comparisons, and data assessment at the user level. Secondary elements are primary data review by the user, performance evaluation samples, field audits, laboratory audits, and tape audits. None of the elements are required by the Corps, though the primary elements are highly recommended. With inclusion of at least some of these activities in District projects, questions and concerns about data quality can be addressed more readily.

Split sample analysis is frequently one of the data quality activities that are used by projects. By selecting this element, project personnel are also able obtain information concerning sample handling directly from the quality assurance laboratory. Data obtained from the primary laboratory and the quality assurance laboratory are then also available for comparison. Thus through selection of one of the QA elements, two more could be readily obtained.

The Environmental Chemistry Branch of the Engineer Research and Development Center is the Corps resource for split sample analysis and associated quality assurance elements. When the Branch (then known as the Missouri River Laboratory) first became involved with quality assurance, provided services were limited to split sample analysis, sample handling quality assurance, and primary/QA data comparisons. In recent years, though, the Branch's role in the Corps environmental program has expanded to include performance of all the twelve quality assurance activities detailed above. Through this expansion of services, Corps project personnel are able to obtain all their desired quality assurance elements from one facility.

Since the Branch provides such a wide range of quality assurance services, we are able to use our comprehensive project knowledge to assist Corps Districts in several ways. In some instances, District personnel have come to us for help in assessing data usability. In other instances, our work uncovered problems with primary laboratory performance that would jeopardize data integrity or completion of the project. These services are the expected benefits of the corporate quality assurance program. Another benefit is the ability to communicate the quality and usability of project data to Federal, State, local, and other stakeholders and partners. A specific example is participation in a restoration advisory board meeting to answer stakeholder questions about data flags, laboratory comments, and other analysis-related concerns. By improving stakeholder confidence in and understanding of findings, all these services directly support projects by resolving problems that are related to usability of data for its intended purpose.

The Corps of Engineers works with local restoration advisory boards (RAB) to exchange information and develop plans for restoration of closed military bases for civilian re-use. Recently, a Corps District was concerned about a RAB's interpretation of laboratory data for a local site investigation. The quality of the data used to make environmental decisions was a prime concern for RAB members. The RAB membership included people with technical backgrounds, but, overall, the language of the laboratory's technical report was a barrier to member's understanding of the analytical results. None of the project personnel who regularly participated in the RAB meetings had sufficient understanding of typical data packages and environmental analytical laboratory practices to adequately answer RAB member's questions. To minimize misunderstanding, contention, and confusion, the District decided that a person with direct experience with laboratory procedures and the quality assurance systems of both the Corps and commercial laboratories was needed to answer questions. The District requested that an Environmental Chemistry Branch QA officer attend the RAB meeting for this purpose.

The QA officer's primary role was to explain case narratives and data flags included in the project's primary laboratory results reports. Review of the data packages provided by the commercial laboratory prior to the RAB meeting showed no significant quality control deficiencies or laboratory error. The RAB members, however, were troubled by the presence of "J" and "B" flags in previous data packages, and were concerned that some samples required dilution. In one member's estimation, these flags indicated that the laboratory was making excuses for poor performance. Another significant RAB concern was that a laboratory might have transposed numbers when converting instrument raw data to final results reports. The RAB requested copies of the laboratory's raw data, including calibration data, sample preparation logs, and analytical run logs for project samples, with the intention of verifying the correctness of the reported results. Each question and concern was on a fundamental, routine procedure that, while easily understood by analytical environmental chemists, suggested significant problems to the RAB members.

The idea to have a QA expert present at the RAB meeting was sound, but the implementation was a limited success. First, the culture of the RAB led to delays during the meeting that prevented sufficient time for adequate discussion of the data. RAB members expressed mistrust and irritation at several points during the meeting, starting from the introduction of a facilitator. Resolution of issues such as these consumed most of the meeting. Secondly, the discussion of the laboratory results was limited to only 15 minutes at the end of the meeting. There was not sufficient time for the members to review all the results and formulate questions. Also, the questions that were framed did not cover enough of the unease to alleviate the concerns held by the RAB. Thirdly, the follow-on meeting was scheduled to occur two months later. This delay between receipt of the data and response to concerns could only add to the general frustration of experienced by the RAB members and project personnel.

Resolution of problems such as these is difficult and will require significant effort. These difficulties are not limited to the project described here, though. To improve stakeholder confidence in environmental decisions, a QA representative should be included as part of the project team at the very start of a project, and should be part of the team that interacts with stakeholders. Incorporation of a QA professional would emphasize the value of a quality assurance system to the project personnel and serve to minimize misunderstandings with the public early in project. Stakeholder concerns tended, in the situation described here, to be basic and easily answered. But because the questions went so long unanswered, they created a negative impact on the project that led to delays and inefficiency. The QA representative, if involved in a project from the planning phase through the stage where data are used to make decisions, as is suggested by comprehensive use of the US Army Corps of Engineers quality assurance program elements, would be a resource for overall improvement of the quality and efficiency of an environmental project.

For more information, contact:

Denise K. MacMillan, Environmental Chemistry Branch,
Army Engineer Research and Development Center,
420 South 18th Street, Omaha, NE 68102-2586
Phone: (402) 444-4304, Fax: (402) 341-5448
e-mail: denise.k.macmillan@nwo02.usace.army.mil

A LOTUS NOTES APPLICATION FOR PREPARING, REVIEWING, AND STORING NHEERL RESEARCH PROTOCOLS

Ron Rogers, Jesse Mabellos,
USEPA,National Health and Environmental Effects Research Laboratory

Upon becoming QA Manager of the Health Effects Research Laboratory (HERL) in 1990, Ron became aware of the need to simplify and streamline the research planning process that Laboratory Principal Investigators (PIs) faced. Appropriately, animal studies require close scrutiny, both in planning and in implementation. However, the planning process in place at HERL at that time involved three separate resource intense, overlapping/redundant, and yet divergent.protocol requirements. In order to comply with the Animal Welfare Regulations and Public Health Service Policy and to maintain AAALAC accreditation of our research program and animal facilities, PIs prepared detailed Laboratory Animal Project Review protocols (LAPRs) for each study in which they would use laboratory animals. These protocols were reviewed for approval by the Institutional Animal Care and Use Committee (IACUC). Each PI who planned to use hazardous biological or chemical agents in their research prepared a detailed Health and Safety Research Protocol for Hazardous Agents, which was reviewed for approval by the Laboratory Safety Committee. The key job of the HERL QA Manager was to ensure compliance with EPA Order 5360.1, which requires that each project be described in an approved QA Project Plan (QAPP) – the third research planning document. There had to be a better way!

Over the next 8 years, little was accomplished to address this widely recognized need to streamline this process. Then, in 1998, the National Health and Environmental Effects Research Laboratory (NHEERL), which was formed in 1995 by combining HERL and four ecological effects research laboratories, decided to employ Lotus Notes as the major platform for e-mail and a host of other Lab-wide functions. With that, the time had finally come to tackle in earnest the protocol merge task! In late 1998 a workgroup was convened to do so, consisting of nine NHEERL stakeholders representing the interests of QA, IACUC, Health & Safety, and the PIs. Since that time, four others with new QA or IACUC roles have been added to the workgroup.

The protocol workgroup developed a design that, in a modular fashion, incorporates all the IACUC, Health & Safety, and QA requirements into a single protocol that is developed within Lotus Notes and circulated electronically for the three sets of reviews and approvals. The system includes a Notes version of a “chatroom” that is designed to alleviate some of the burden on the IACUC who must carry out increasingly rigorous committee reviews of the protocols. Approved protocols will be stored in a repository of active protocols and an archive of expired protocols. The Notes multipurpose research protocol application has been developed to the point of first phase beta testing. When the system is fully completed (target date for NHEERL-RTP: early FY2002) and approved for implementation, information from these protocols will be automatically shared with related information management (IM) databases that have been or are being developed to track at the individual protocol level (a) QA information relative to QA reviews, corrective actions, due dates, etc.; (b) authorizations to use hazardous agents in research studies; and (c) an inventory of laboratory animals authorized, ordered, on-study, and expired.

Future plans for the system include its expansion to accommodate human studies protocols carried out by NHEERL's Human Studies Division, studies that require review and approval by an Institutional Review Board composed of non-EPA individuals. The system is also being developed with an eye toward accommodating the protocol requirements of the NHEERL Ecology Divisions, perhaps beyond, given the current emphasis on cross-Lab research projects.

IMPLEMENTATION OF QUALITY ASSURANCE ON MULTILABORATORY STUDIES WITHIN THE U. S. EPA

Thomas J. Hughes[1], Brenda Culpepper[1], Nancy Adams[2], and John Martinson[3], [1]National Health and Environmental Effects Research Laboratory (NHEERL), [2]National Risk Management Research Laboratory (NRMRL), and [3]National Environmental Research Laboratory (NERL), U.S. EPA.

Abstract: The purpose of this talk is to explain the approach the U.S. EPA has taken on quality assurance (QA) of research studies conducted within the Agency. The U. S. EPA, Office of Research and Development, was reorganized in 1995 into National Laboratories and Centers, and since that time the scientific collaboration among the National Laboratories and Centers has significantly increased. Consequently, the EPA-ORD quality assurance community has sought to reach a consensus on the mechanisms for QA activities on such research studies, which tend to be large multidisciplinary, multiyear studies. An operating procedure (OP) for multilaboratory studies was therefore written by QA personnel in the three National Laboratories identified in the header, in collaboration with the National Center for Environmental Assessment (NCEA) and the National Center for Environmental Research (NCER). This OP is entitled "Coordination of QA Efforts Across EPA Organizations for Multilaboratory/Center EPA Research Studies." At the present time, this OP is in final review by the participants, and will be signed and approved by all parties shortly. This OP provides general guidance to all parties concerned, and has been written so as not to interfere with specific mandates of any of the involved National Laboratories or Centers. The OP states that an umbrella QA Project Plan (QAPP) for such multilaboratory projects is the responsibility of the lead Principal Investigator (PI), who will be determined after consultation with all study personnel and QA Managers (QAMs) and Directors (DQAs). This umbrella QAPP will consist of individual sub-plans linked together under an overall format determined by the lead PI, who will also determine the QA categories for the study, after consultation with their QAM, DQA and management. At the end of the project, the lead PI will collect all QA reports from the study and write a QA Summary for the final report. The OP also discusses roles and responsibilities of study participants, encourages frequent communication among all study participants, and contains a flowchart of overall QA activities for the project. This talk will discuss the specific details in this OP, and describe how this OP for multilaboratory research studies has been employed in studies where NHEERL is the lead organization.

A SOLUTION FOR THE NEED TO HAVE DEFENSIBLE, DOCUMENTED, QUALITY DATA TRACEABLE TO AN ACCREDITED LABORATORY AT A LOW COST

Paul Groff, U.S. EPA

Abstract: EPA's Office of Research and Development (ORD) obtains data to understand fundamental pollution formation and control mechanisms, to identify sources of pollution, to support regulation, to create emission inventories, and to develop new pollution control technologies. These data require measurements of quality that is known and documented (ideally from an accredited laboratory) so that conclusions can be drawn with data qualifiers. These data qualifiers are essential for identifying applicability, implications, and limitations of the conclusions. At times this type of information provides evidence in litigation where every aspect of data defensibility will be challenged. For these reasons it is critical that data be obtained using sound methods (standard methods when possible) and that the measurements in the methods be traceable to a recognized standard such as those provided by the National Institute of Standards and Technology (NIST). At the Air Pollution Prevention Control Division (APPCD), the on-site metrology laboratory provides calibrations traceable to NIST, but so far the laboratory has not obtained third party evaluation (accreditation). NIST developed the National Voluntary Laboratory Accreditation Program (NVLAP) that is in full conformance with the standards of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), including ISO/IEC Guides 25 and 58. This paper discusses the NVLAP accreditation process, its importance to APPCD, and its cost.

LESSONS LEARNED IN PREPARING METHOD 29 FILTERS FOR COMPLIANCE TESTING AUDITS

Joan T. Bursey, Ph.D., Eastern Research Group, Morrisville, NC
Clyde E. Riley, Emission Measurement Center, U.S. Environmental Protection Agency,
Judith E. McCartney, Eastern Research Group, Morrisville, NC
Mr. Robert Martz, Eastern Research Group, Inc.

Abstract — Companies conducting compliance testing are required to analyze audit samples at the time they collect and analyze the stack samples if audit samples are available. Eastern Research Group (ERG) provides technical support to the EPA's Emission Measurements Center's Stationary Source Compliance Audit Program (SSCAP) for developing, preparing, and distributing performance evaluation samples and audit materials. These audit samples are requested via the regulatory Agency and include spiked audit materials for EPA Method 29 - Metals Emissions from Stationary Sources, as well as other methods.

To provide appropriate audit materials to Federal, State, tribal, and local governments, as well as agencies performing environmental activities and conducting emission compliance tests, ERG has recently performed testing of blank filter materials and preparation of spiked filters for EPA Method 29. For sampling stationary sources using an EPA Method 29 sampling train, the use of filters without organic binders containing less than 1.3 µg/in.^{2} of each of the metals to be measured is required. Risk Assessment testing imposes even stricter requirements for clean filter background levels. Three vendor sources of quartz fiber filters were evaluated for background contamination to ensure that audit samples would be prepared using filters with the lowest metal background levels. A procedure was developed to test new filters and a cleaning procedure was evaluated to see if a greater level of cleanliness could be achieved using an acid rinse with new filters.

Background levels for filters supplied by different vendors and within lots of filters from the same vendor showed a wide variation, confirmed through contact with several analytical laboratories that frequently perform EPA Method 29 analyses. It has been necessary to repeat more than one compliance test because of suspect metals background contamination levels. An acid cleaning step produced improvement in contamination level, but the difference was not significant for most of the Method 29 target metals.

As a result of our studies, we conclude:

- *Filters for Method 29 testing should be purchased in lots as large as possible.*
- *Testing firms should pre-screen new boxes and/or new lots of filters used for Method 29 testing.*
- *Random analysis of three filters (top, middle, bottom of the box) from a new box of vendor filters before allowing them to be used in field tests is a prudent approach.*
- *A box of filters from a given vendor should be screened, and filters from this screened box should be used both for testing and as field*

blanks in each test scenario to provide the level of quality assurance required for stationary source testing.

Eastern Research Group (ERG) provides technical support to the EPA's Emission Measurements Center's Stationary Source Compliance Audit Program (SSCAP) for developing, preparing, and distributing performance evaluation samples and audit materials. For the past four years, ERG has provided contractor support to the EPA in the area of compliance audits.

Companies conducting compliance testing are required to analyze audit samples (if available) at the time they collect and analyze stack samples using any of several EPA test methods. To provide appropriate audit materials to Federal, State, tribal, and local governments, as well as agencies performing environmental activities and conducting emission compliance tests, these audit samples are requested via the regulatory Agency and include spiked audit materials for EPA Method 29 - Metals Emissions from Stationary Sources, as well as other methods. Consistent with the components of the EPA Method 29 sampling train, audit materials are supplied as spiked filters and as spiked aqueous media.

In performing compliance testing, field testing personnel and laboratory personnel collaboratively apply approved EPA sampling and analytical methods to determine whether a given facility is in compliance with environmental regulations. A "successful" compliance test (from the point of view of the affected facility) demonstrates that the facility is complying with applicable regulations – i.e., levels of tested materials are measured below the level that will trigger remedial activity and repeated testing on the part of the affected facility. It has been brought to our attention that several field groups and testing firms have been experiencing test failures because of so-called "dirty filters" with high background levels that yield "out of compliance" results for certain metals on blank and sample filters. EPA Method 29 states that the filters used in testing shall contain less than 1.3 $\mu g/in^2$ of each of the metals to be measured.[1] Risk Assessment testing may impose even stricter requirements for cleanliness of filter background. This target level for cleanliness has not been achieved in several cases of "out of the box" filters used in sampling for metals at stationary sources.

Examples of high levels of filter contamination in two different field studies are shown in Table 1. These data show that significant levels of arsenic, barium, and other metals were found in "blank" filters from field sampling efforts. Two different filter lots from two different vendors were used in tests conducted at two separate geographic sources. The metals observed were not expected to be found at the source, and the analytical laboratory rechecked each measurement to verify that there was no laboratory contamination or extenuating circumstances related to the analysis process. The levels of contamination in the two filters were so great that expensive field tests had to be repeated to verify the results. More than one compliance test has been repeated due to suspect metals background contamination levels. Several analytical laboratories had observed and reported high levels of background contamination on filter media used for metals sampling and analysis. In some cases, the levels of filter blanks have been too high for an accurate determination of the source contribution, and in other cases, the final results from field work had suspicious levels of contamination. Background levels between vendors and within lots of

[1] Method 29 - Metals Emissions from Stationary Sources, Code of Federal Regulations, Title 40, Part 60, Appendix A, February, 2000.

filters from the same vendor showed a wide variation, confirmed through contact with several analytical laboratories that perform EPA Method 29 analyses. A background study was initiated by ERG to investigate these claims.

Three selected vendor sources of quartz fiber filters were evaluated by ERG for background contamination in order to ensure that our audit samples would be prepared using filters with the lowest possible metal background levels. In each case, filters were purchased and three random filters chosen from an individual vendor's box were digested separately, the digests combined, and analyzed according to EPA Method 29 procedures. The results are reported in Table 2 as per filter values. The apparent background level of the filters varied greatly from vendor to vendor, with one vendor delivering "new clean" filters with surprisingly high levels of barium and phosphorus.

Filters were also evaluated to gain additional insight into the per filter variation of blank filters. The "hits" from Vendors A and B in Table 2 were tested to see if there was significant variation from filter to filter. Only those metals that were found at levels above the analytical method detection limit were selected and three filters were evaluated to look at the differences. Results are shown in Table 3. The filters were reasonably consistent, but the decision was made to use the average of three analyzed filters for future determinations rather than using a single filter.

While the best filter shown in Table 3 was reasonably adequate for spiking experiments, a procedure was developed by ERG to clean new filters and that cleaning procedure was evaluated to see if a greater level of cleanliness could be achieved using an acid rinse with new filters.

Acid cleaning had been suggested by a few specialists in the inorganic analysis field, but no specifics had been documented. Batches of 25 - 50 new filters were acid washed as a group multiple times with a 10% nitric acid solution in a Büchner filtration apparatus. Filters were pre-rinsed with deionized water, then immersed in 10% nitric acid, which was applied three times to the filter group. Filters were never allowed to dry while loaded in the Büchner filter, to avoid passive sampling of room air through the filters. The filters were immersed and rinsed thoroughly with deionized water, and gently dried individually in a clean laboratory oven.

The comparison of the blank versus acid washed filters is shown in Table 4. Acid cleaning produced improvement in background contamination level, but the difference was not significant for most of the listed Method 29 target metals. Again, three random filters were chosen from a vendor's box, then digested separately, combined, analyzed, and compared to three random filters chosen from the acid washing treatment. Barium, chromium, and zinc levels were slightly improved by the acid treatment, while the other elements were essentially unchanged in their per filter concentrations. While we believe that the filter washing is effective, it does not appear warranted for filter vendor batches that are already clean enough to meet Method 29 cleanliness criteria. Perhaps acid washing is a technique that could be applied by the vendors to produce a more consistent quality filter for use in EPA Method 29 metals sampling.

As a result of our EPA Method 29 studies, we have reached the following conclusions:

- A vendor providing "quartz" fiber filters designated as <u>EPA</u> <u>Method</u> <u>29</u> or <u>Metals Sampling</u> filters does not necessarily provide filter media that is clean enough to meet method specifications. Consulting other analysts and comparison shopping is recommended.

- Filters for EPA Method 29 testing and spiking should be purchased in lots as large as possible (100 - 200 filters or more) to allow a full set to be evaluated for cleanliness and the entire lots certified as acceptable for spiking studies, field use, or laboratory studies. A large single lot is the most convenient way to use in spiking or ongoing field testing. Filters from the same lot and the same vendor should be used for testing, field blanks, and laboratory blanks.

- Testing firms should pre-screen new boxes and/or new lots of filters used for Method 29 testing. We are aware of several firms that are sending all of their filters off to analytical laboratories to "pre-screen" the lots of filters and avoid contamination problems at the end of an expensive field test or compliance study. While this extra testing is expensive, it is much less expensive than the repeating of an entire field test.

- We agree with fellow laboratories that randomly checking and analyzing three filters (top, middle, bottom of the box) from a new box or new lot of vendor filters before allowing them to be used in field tests is a prudent approach. The "cleanliness" of the filters can be documented as an initial quality assurance step in the test sequence or spiking study.

- The screened boxes of filters in combination with filters chosen and used as field blanks should be used in each test scenario to provide the level of quality assurance required for stationary source testing. Screening the boxes, combined with the careful handling of the filters, will not eliminate all filter contamination issues, but it will avoid the very large background levels that some testing firms have encountered.

Table 1. Examples of High Levels of Filter Contamination

Metal of Interest	Contaminated Blank Filter 1 (µg/filter)	Contaminated Blank Filter 2 (µg/filter)	Laboratory Blank Filter (µg/filter)
Sb	**16**	**26**	<0.4
As	**513**	**853**	0.5
Ba	**107**	**259**	**3.4**
Be	0.2	0.2	<0.1
Cd	<0.1	<0.1	<0.1
Cr	**4.7**	**8.4**	0.2
Co	0.4	2.2	<0.1
Cu	2.2	3.2	0.4
Pb	**10**	**19**	0.6
Mn	**27**	**57**	<0.75
Ni	2.7	**23**	0.25
Zn	**14**	**54**	1.7

Filters #1 and #2 were from different vendors. The Laboratory Blank Filter was from a third vendor.

Table 2. Quartz Filters Evaluated for Background Contamination

Metal	Symbol	Vendor A (μg/filter)	Vendor B (μg/filter)	Vendor C (μg/filter)
Antimony	Sb	< 0.5	1	< 0.5
Arsenic	As	< 0.5	< 0.5	< 0.5
Barium	Ba	**14**	**9**	**134**
Beryllium	Be	< 0.02	< 0.02	< 0.02
Cadmium	Cd	< 0.01	< 0.01	< 0.01
Chromium	Cr	1.4	1.8	2.5
Cobalt	Co	< 1.5	< 1.5	< 1.5
Copper	Cu	< 2	< 2	< 2
Lead	Pb	1.4	0.4	1
Manganese	Mn	< 1	1	2
Mercury	Hg	< 0.4	< 0.4	< 0.4
Nickel	Ni	< 0.5	0.7	< 0.5
Phosphorus	P	< 30	< 30	**114**
Selenium	Se	< 0.3	< 0.3	< 0.3
Silver	Ag	< 0.02	< 0.02	< 0.02
Thallium	Tl	< 0.5	< 0.5	< 0.5
Zinc	Zn	**14**	**4**	**15**

Table 3. Filter Evaluation

Metal	Filter #1 (μg/filter)	Filter #2 (μg/filter)	Filter #3 (μg/filter)	Average (μg/filter)
Barium	6	3	2	3.67
Chromium	2.2	2.1	2.2	2.17
Lead	0.4	0.4	0.4	0.40
Zinc	2	2	4	2.67

Filters were from Vendor B.

Table 4. Blank versus Acid Washed Filters

Metal	Symbol	Blank filters (μg/filter)	Acid washed filters (μg/filter)	Method blank criteria [a] (μg/filter)
Antimony	Sb	< 0.7	< 0.7	18.4
Arsenic	As	< 0.5	0.5	18.4
Barium	Ba	3.3	1.8	18.4
Beryllium	Be	< 0.05	< 0.05	18.4
Cadmium	Cd	< 0.05	< 0.05	18.4
Chromium	Cr	3.1	2.6	18.4
Cobalt	Co	< 1.0	< 1.0	18.4
Copper	Cu	< 0.5	< 0.5	18.4
Lead	Pb	< 0.5	< 0.5	18.4
Manganese	Mn	< 1.0	< 1.0	18.4
Nickel	Ni	< 1.0	< 1.0	18.4
Selenium	Se	< 0.6	< 0.6	18.4
Silver	Ag	< 0.02	< 0.02	18.4
Thallium	Tl	< 0.5	< 0.5	18.4
Zinc	Zn	2.9	2.0	18.4

[a] 4.25 inch diameter filters (14.19 sq. in.) were used for these tests.

PASSIVE DIFFUSION BAG SAMPLERS

Maj. Jeff Cornell, Dr. Don Vroblesky, Dr. Javier Santillan*, U.S. Air Force

Abstract: Passive diffusion bag (PDB) samplers are suitable for obtaining representative concentrations of volatile organic compounds in groundwater from monitoring wells. A typical PDB sampler consists of a low-density polyethylene lay-flat tube closed at both ends and containing deionized water. The sampler is positioned at the target location in the aquifer by attachment to a weighted line. The PDB samplers equilibrate within approximately 48 hours for TCE and PCE, however vinyl chloride and some chloroethanes may require between 96 and 168 hours to equilibrate. The samplers should be allowed to remain in the well a minimum of two weeks prior to recovery to allow the well water to restabilize following sampler deployment, and dilution generated by the "absorption" by the PDB sampler. Recovery consists of removing the samplers from the well, and immediately transferring the enclosed water to 40-milliliter sampling vials for analysis.

The method has both advantages and limitations. Advantages include the potential for PDB samplers to eliminate or substantially reduce the amount of purge water associated with sampling. The samplers are relatively inexpensive and easy to deploy and recover. Because PDB samplers are disposable, there is no downhole equipment to be decontaminated between wells and there is a minimum amount of field equipment required. The samplers also have the potential to delineating contaminant stratification in the open or screened intervals of observation wells where vertical hydraulic gradients are not present.

A possible disadvantage of the samplers is that they integrate concentrations over time. Depending on the compound of interest, this time may range between about 48 to 168 hours. The samplers are not applicable for all volatile compounds. They are not effective for inorganic ions, for highly soluble organics such as methyl-tert-butyl ether, or poorly soluble organic compounds. An additional disadvantage is water must be freely flowing through the well screen for the samplers to be effective. VOC concentrations in PDB samplers represent concentrations in the vicinity of the sampler within the well screen or open interval. This may be a limitation if the ground-water contamination is above or below the screen, or not in the interrogated sample intervals. If there are vertical hydraulic gradient in the well, then the concentrations in the sampler represent the concentrations in the water flowing vertically past the sampler rather than in the formation immediately adjacent to the sampler. Multiple PDB samplers may be needed in chemically stratified wells or where flow patterns through the screen change as a result of ground-water pumping or seasonal fluctuations.

MEASUREMENT UNCERTAINTY FOR ENVIRONMENTAL PROGRAMS

Marlene O. Moore, Advanced Systems, Inc.

Abstract — Currently the primary topic of discussion for many testing laboratories in the United States and the world is measurement uncertainty. Except in a limited number of testing fields, such as calibration, radiochemistry and some biological studies, the uncertainty of measurements is not commonly defined or practiced by testing laboratories. With the recent publication, adoption and implementation of ISO/IEC 17025, testing laboratories must address the understanding, documentation and evaluation of measurement uncertainty. ISO/IEC 17025 requires the laboratory to have and apply procedures for measurement uncertainty. It is noted that the ISO/IEC 17025 definition of uncertainty has been defined as stated in the "Guidelines for Expression of Measurement Uncertainty" (GUM). This uniform definition requires the reevaluation of the uncertainty expressions being used by all laboratories when expressing measurement results. The presentation will include a review of the definition of measurement uncertainty define internationally and alternatives under consideration for testing laboratories worldwide with emphasis on environmental applications.

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First we will review the definition for measurement uncertainty, second we will review some of the methods used for determining uncertainty and finally we will look at the application of measurement uncertainty for environmental programs.

Measurement Uncertainty Definition

Definition of terms is critical when discussing uncertainty. The definitions used for measurement uncertainty today is based on the international metrological definition. Over the past several years a uniform definition for measurement uncertainty has evolved and been adopted worldwide. This definition is found in "Guidelines for Expression of Measurement Uncertainty" (GUM). Laboratory accreditation bodies have adopted this guideline to ensure a uniform application and understanding for measurement uncertainty. However, some in the testing laboratory community believe this definition is not applicable to testing laboratories and that the implementation of this measurement uncertainty standard by testing laboratories is too costly and not practical. In addition the statistical application and evaluation of testing data is not understood by most chemists, biologists and other testing laboratory scientists.

A person's academic, technical and work background will play a significant role in the understanding of uncertainty. Here are a few definitions obtained from a variety of sources.

Absolute Uncertainty: the instrument or equipment reliability as defined by the manufacturer, e.g.: the balance permits no better operation than ±0.05 g. (Chemistry textbook 1969)

Relative Uncertainty: Expression of reliability defined as the fraction obtained by dividing the absolute uncertainty by the value of the result. (Chemistry textbook 1969)

Uncertainty of measurement: parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. (VIM 3.9)

Combined standard Uncertainty: standard uncertainty of the result (y) of a measurement when the result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with these quantities (GUM 2.3.4)

Expanded Uncertainty: Quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonable be attributed to the measurand. Obtained by multiplying the combined standard uncertainty by a coverage factor. Usually expressed as 'k". (GUM 2.3.5)

When discussing and using scientific terms be sure that the client, regulatory agency, accrediting body, and others use the terms in the same way. Many clients, regulators and other data users express these terms based on various in-house and externally defined programs. Knowing the reason for the test and the client proposed application of the data should ensure that all parties involved with the data apply the same terms.

In environmental programs, measurement uncertainty is expressed for instrumental uncertainty such as radiochemistry, and for probability distributions such as biological testing. However current environmental programs do not currently define the reporting of measurement uncertainty. Measurement uncertainty must include sampling, site characteristics, matrix effects and the laboratory effects. Therefore the definition and determination of measurement uncertainty is required by the data user and is not a laboratory-generated value. The laboratory provides the data for calculating the uncertainty, but the data user must generate and define the measurement uncertainty for environmental reporting and decisions. This is better understood when the steps for determining uncertainty are reviewed.

Measurement Uncertainty Methods

The uncertainty provides the data user with the interval about the result. This interval expresses the random and systematic effects on the measurement. The values present the variability of the result, thus providing a level of confidence when making a decision using the result. With the adoption of a single standard, (GUM) for defining uncertainty for the international presentation of data, the use of the plus/minus symbol should become more common place in the future.

Uncertainty expresses the range of values that could reasonably be attributed to the measured quantity. The expanded uncertainty provides the level of confidence that the value actually lies within the range defined by the uncertainty interval.

The estimating of uncertainty is a quantitative indication of the quality of the result. This estimation provides the data user with the confidence to allow comparability. This is needed in order to reduce trade barriers, allow accreditation bodies an objective approach to resolving data comparability complaints and provide the data user with information related to the risk in making a decision.

For example, one accredited laboratory performs method A and determines the result to be 4.5 or within specification (< 5.0). A second accredited laboratory performs method A on the same product and finds a result of 5.3 or outside the specification (> 5.0). If both laboratories have evaluated their uncertainties for the method, the data user can request this information for method A. Although other factors may be prevalent, if the uncertainties overlap, it can be determined that the test method results overlap the specification criteria resulting in this seeming acceptable and unacceptable product. If they do not overlap, the evaluation by the data user should find other variations resulting in the product disparity in results. In time, if both labs are performing the same method they should have determined similar uncertainties. However, this will only become possible when the reference method A states the uncertainties achieved with the method based on inter or intra laboratory comparison data and a uniform method for determining uncertainty is defined.

Currently there are several ways to determine the uncertainty of the measurement and more are being proposed. This paper presents several methods which use the internationally definition of uncertainty. Before any calculations are completed the measurement must be evaluated then the calculations are performed. This has been presented in a seven step process.

1. Write down what is being measured, including any relationship between the measurand and the parameters upon which is depends. For example measuring nitrate. Standard used is a potassium nitrate salt. The measurand may be expressed as nitrate as NO_3 or NO_3 as N. Document how the final result is defined by the calibration standard or spiking standard.

2. State or refer to the SOP defining all measurement conditions. If your SOPs reflects what is included in the process and all the conditions of the test method is defined, then summarize the conditions and processes that contribute to the uncertainty. These include, calibration equipment or standard uncertainty, environment, operator, sample or item under test, and procedure.

3. List possible sources of uncertainty, i.e. drying or primary standard, weighing, personnel ability to weigh and make volumetric measurements, reading the analog dial on the spectrophotometer, wavelength drift, glassware variations, etc.. This listing from Item 2 indicates the components under consideration. Detailed studies are not required on any one or all of the contributors, but a listing of all assumptions should be documented.

4. Consolidate the components. Look for interdependence and eliminate any components that overlap. This review must ensure that the components are independent variables.

5. Measure or estimate the size of the components. If the random component is known or expected to be significant perform measurements to determine the components standard uncertainty. This can be compared to the listed systematic components of uncertainty to evaluate the random compared to the systematic effects.

Review all the components and convert all components to the units of the measurand. This requires a technical understanding of the measurement process. In some cases the values are converted to percent or a defined unit and the final result's uncertainty expressed in that unit. For example if the percent recovery is used for the LCS and the uncertainty is expressed as percent the uncertainty for each value is calculated from the result. The result is 12.6 mg/L with the uncertainty budget of $\pm$ 10%, then the result is expressed as 12.6 $\pm$ 1.3 mg/L.

6. Convert the components to the standard uncertainty. For random error divide the standard deviation by the square root of the number of measurements. For systematic determine if normal, or other distributions exist.

7. Calculate the combined uncertainty and the expanded uncertainty.

Some groups are attempting to use control charts for determining the uncertainty of the measurement. However, the use of control charts does not necessarily express the measurement uncertainty. In fact the control chart plots the stability of the measurement. Caution must be used when evaluating these charts for uncertainty since many control charts do not include all sources of bias and precision. The control chart should be used to evaluate the stability of the measurement to ensure that blunders or outliers are not incorporated into the measurement result. The control chart is used to ensure the process is in control and is useful for ensuring the quality assurance program is effective. The control chart provides the information regarding the stability of the measurement. The measurement must be stable in order to calculate the uncertainty. The GUM assumes the measurement is stable and the error (true value - observed value) is limited. If this is not the case, the uncertainty should be qualified.

Another method for determining the uncertainty of the test method is based on a recent paper found in "Environmental Testing & Analysis" Nov/Dec. This approach allows the determination of the method uncertainty using the LCS with a bias correction. Others are determining the uncertainty of the method by using over 50 LCS data points and calculating the standard uncertainty. These methods allow the laboratory to evaluate it test method over time, but do not provide any information on the measurement uncertainty. That is the environmental sample analysis uncertainty is not one of the components evaluated.

The presentation of the derivation of the uncertainty may be presented as an uncertainty budget or using cause effect diagrams. This method for determining uncertainty present all the components associated with the method and list these in a fish bone diagram or Ishikawa diagram. Another term for this type of diagram is a cause effect diagram.

For more complicated analysis, it is preferred to use this type of diagram in order to present all components. The Eurachem/Citac Guide provides a detailed discussion of this type of presentation. The Eurachem document provides specific examples for presenting the evaluation of uncertainty. The diagram presents a graphical presentation of the uncertainty budget.

This approach takes the existing QC elements found in all environmental chemical measurements and estimates the uncertainty for a single measurement. The uncertainty includes both laboratory and field sampling activities. In most environmental data the uncertainty for the field is often ignored even though many statistical evaluations indicate that the majority of the error is attributed to the field activity.

The objective statistical evaluation of the uncertainty for field activities has not been possible until now. Using this new technique, it is possible to back out each of the components and evaluate them separately. Thereby allowing the overall estimation of uncertainty for measurements for a specific sample.

The nested approach determines the uncertainty of the sample being representative of the population. A probabilistic sampling approach along with the uncertainty of measurement should be combined for the uncertainty of the measurement for the site to be representative of the population.

Environmental Programs Application

Estimation of measurement uncertainty may be achieved by a nested hierarchical study of uncertainties inherent in each component of the analytical process. The nested study approach applies mathematical techniques defined as **backing-out, normalization**, and **integration** to estimate component and sample uncertainties. These techniques are simple mathematical operations that correct for systematic errors and estimate analytical uncertainty inherent in the random variation of test measurements.

The approach estimates the uncertainty of:

A. intrinsic instrumental test measurement method uncertainty
B. inherent spike uncertainty and spike preparation uncertainty
C. preparation method uncertainty
D. matrix interference uncertainty
E. sample collection uncertainty
F. sampling strategy uncertainty
G. sampling site parameter (target analyte) uncertainty

Method uncertainty is A and C.
Population uncertainty in the environment is G.
Measurement uncertainty is estimated by combining A, B, C, and D

The expression of the uncertainty of the measurement allows data comparability. As environmental programs move away from the regulatory method comparison to a action level or maximum contaminant level the need for a uniform basis of comparison is required. The expression of uncertainty provides the data user with the range possible from the measurement.

Regulatory programs will need to define the error (true value from observed value) and the uncertainty of the measurement expected before making a decision. Some programs define the expected recovery of the contaminant using any method. Such as at least a 60% recovery must be achieved with the test method. This may be difficult since, current methods do not always achieve this goal.

Decisions based on a single number without the stated uncertainty are not meaningful in a performance based regulatory program. Knowing the value and the expressed uncertainty is outside the specification limit allows for a clear decision. The specification criteria may be client, regulatory or product driven. The specification limit does not always have to be a range. In many cases the specification is a single value that the result must be less than or greater than a single value. The specification limit may be regulatory limit or product acceptance criteria. By expressing the value and the range, it provides the user with the information necessary to understanding any risk or uncertainty associated with making the decision. When the value and the expressed uncertainty is inside or outside the specification, the decision is clear. When the value and its uncertainty are not inside or outside, the decision is not clear. In fact, the chance of making an incorrect decision is more likely.

Without an estimate of uncertainty of the measurement the opinion and interpretation require a significant amount of documentation to justify the decision. In all cases the client and laboratory must agree who is making the decision relative to the data and what are the decision rules that need to be applied to the data when making that decision. Knowing regulatory requirements, industrial standards and conformity assessment criteria is a must before expressing an opinion. Documentation of these decision rules ensures consistent implementation and a documented understanding should future interpretation be required.

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TWO DATABASES IN EVERY GARAGE: INFORMATION QUALITY SYSTEMS

Jeff Worthington, USEPA, Office of Environmental Information

KEY WORDS
information quality, life cycle, value chain

INTRODUCTION

The first automobiles were assembled by hand and no two were alike. Parts were not interchangeable. Invention of the assembly line (Ideafinder 2001) by Ransom Olds (Henry Ford added the conveyer belt) is often cited as an important example of how standardization helped an enterprise achieve success. Standardizing individual parts promoted interchangeability and facilitated maintenance and product reliability. Quality system techniques evolved to support various assembly line processes.

Technical information generators and customers are confronted with a similar problem. Technical database systems are often crafted by a small group. Database elements, data structures, and relationships that give value to information may not be interchangeable between systems. Systems may not be able to directly interact with each other or be comparable. Standardizing data system parts was not a priority.

Now, information workers and the enterprise recognize that information is an important strategic resource for the enterprise and needs to be managed as a resource. Management systems for many enterprises are adapting to support standardization and a centralized framework for all individual components to facilitate information resource access and usability. Successful management reduces the need to “retrofit” data to meet the needs of new users in a different model of the data system. Just as in the automotive industry, an enterprise’s quality system must evolve to support these new approaches to managing information, including technical information.

This paper describes integrating quality systems with both technical science systems and information systems and how the resulting integrated system will ensure quality of production and distribution of technical information as a strategic resource.

Basic techniques that are useful to all quality managers are presented including:

- identifying information quality indicators
- managing information as an enterprise resource
- reconciling information quality with existing quality systems
- assessing information quality

BACKGROUND

Information management quality systems Prior to creation of the USEPA in 1970, Federal agencies were already actively developing and collecting environmental information such as water quality measurements. New EPA programs, with increased analytical technical capabilities including automation and computerization of analytical operations, created a literal deluge of both paper and electronic information. Also, new information sources, such as geospatial information, increased both scope and application of environmental information. Information management and database systems evolved to meet customers' needs in each individual environmental program information application. Quality systems designed for information management were based on identifying functional and data requirements and subsequent design and development of software systems, subject to intensive testing programs. Quality management for hardware systems included assurance of both reliability and maintainability.

The most recent innovation, the Internet, increased access to these growing storehouses of environmental information and changed customers' expectations regarding quality of information.

Technical measurement quality systems

USEPA established formal quality policy in 1984 and re-affirmed policy in 2000 in USEPA Order 5360.1 A1, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, and USEPA Order 5360.1 A2, *USEPA Quality Manual*. These documents provide for quality of environmental measurements, environmental technology development, and use of measurements by secondary users. Guidance development in the specific area of information quality is left to each office to develop relative to their own work efforts and outputs.

Quality and data caught in the middle

Environmental measurement "centered" quality system may treat application of computer technology as a support operation, subservient to the real focus of the process: collection and analysis of environmental samples and information. The required planning document, a Quality Assurance Project Plan (QAPP), may not contain a detailed section describing minimal quality expectations for performance of a computer system. Likewise, quality systems for development of software may not take adequate consideration of the meaning and ultimate use of environmental measurements and supporting quality indicators as a non-depleting resource. The result of this situation is that the "quality of information" may not be adequately measured or known. Quality managers may need to look at unification of disparate quality systems to ensure that all quality interests of the enterprise are adequately captured. For example, a technical measurements quality system takes into account *accuracy* as a measure of the ability of a technical measurement to provide results as close as possible to the actual value. A software quality system may take *accuracy* to mean a demonstration of *freedom from defects* when data are entered into an information system.

Standardization in technical measurements and information

Quality systems are based on and promote use of standard methodology. The EPA quality system is based on a national consensus standard. Environmental analyses are routinely performed according to standardized analytical methodologies (e.g., "EPA Standard Methods). Capture of environmental measurement data and other information into EPA systems has recently been the subject of standardization in the form of *data standards*. To date, the Agency has completed work on the following data standards: biological taxonomy, chemical identification, date, facility identification, longitude/latitude, and SICS/NAIC (business and industry classification).

KEY CONCEPTS

Following are some key concepts to consider when planning integration of disparate quality systems and developing systems which address both production and distribution of technical information.

Concept 1: Recognizing government information as a strategic and national resource

Enterprises, including government Agencies, have focused on providing resources for information and data and laid out authority and responsibility for IT support and operations.   Identification and management of information as a strategic resource is an important aspect to establishing and endorsing formal stewardship in the new millennium. This identification allows organizations to consider how to manage information as a resource.   For example, as a resource, the enterprise may need to look at resource availability, cost, and disposal of the information resource. One unique aspect of information as a resource is that information is not a “consumable” resource. The fact that information is a strategic resource and the fact that it is not consumable greatly impact the type of quality system that should be used when considering production and distribution of this resources.

Many resources used in a manufacturing facility are not reusable. They are produced or purchased and are subject to routine inspections to determine or verify that resources are acceptable for their use in the facility. Non-conforming materials are rejected. In a similar manner, non-conforming information produced as the result of environmental measurement or recording of compliance monitoring may be rejected if information is inspected to determine conformance for acceptability. However, for information, even if the information is not acceptable for its intended use, the enterprise may value and plan to keep the information for other purposes. Also, the very fact that the enterprise has possession of a growing warehouse of data may lead the enterprise to evaluate the use and re-use of this information for new and previously unplanned purposes. In that sense, information resource is not “consumable.” Also, the quality of this resource may be perceived differently. For example, in using this warehoused data, new users may apply new quality indicators, such as the degree to which information describes conditions across a broad geographic area, where information was only originally intended to be used to apply to a specific area for a simple need relative to that area.

Concept 2: Unification generation in information systems

Zachman Framework authors (Zachman, Inmon, Geiger 1997) describe the following evolutionary generations for the computer environment:

- **formation generation** - introduction of the computer to the enterprise
- **proliferation generation** - the enterprise recognizes value and expends significant resources to acquire and support computer systems
- **dispersion generation** - computers and computer operations are dispersed widely throughout the enterprise without a focused effort to manage them

- **unification generation** - where we all should be now, the enterprise shift management focus from managing the computer and associated technologies to managing the environment within which computers operate and to managing data as a enterprises's resource.

USEPA is actively moving from the *dispersion generation* to the *unification generation* of computer systems. Information managers and quality managers focused quality management systems on distinct elements in the *dispersion generation* of the computer environment (and the overall enterprise). For example, quality planning was performed according to the following model:

TABLE: Dispersed quality system foci

Activity	**Quality system focus**
software development	QA planning for software, life cycle development, data/functional requirements, verification and validation of software
hardware	reliability and maintainability of hardware, purchasing requirements
technical information development	QA planning for science activities, scientific method, measurement objectives, verification of conformance to quality control criteria
information collection into a data system	data integrity checks, error correction protocols
data warehouses	gap identification, completeness, consistency

In addition to the generally disparate areas identified in the table above, in each activity area, the quality system activities are often performed according to different methodologies. For example, for technical information, development activities are often different for each type of information. Unification of all these activities in a single quality system should be consistent with efforts to unify information systems.

Concept 3: Understanding needs and expectations for information quality

An enterprise planning to actively managing information quality must know what **information quality** means to the enterprise. That knowledge is based on understanding needs and expectations of customers for information. Information customers may include any or all of the following:

- enterprise knowledge workers
- enterprise managers
- clients

As in any other quality model, quality managers need to work with these parties to document their needs and expectations. Some typical types of features and characteristics of information that are of interest to customers include various aspects of either *production* or *distribution* of information or both. Some features and characteristics that may be of interest are discussed in following sections.

Concept 4: Identifying information quality value chains

"A chain is only as strong as its weakest link." Information quality characteristics are not simply measured attributes like those attributes that could be measured of an end product in a manufacturing process, such as an automobile. Information quality is both *additive* and *separate.* It is *additive* because each link in the process may affect the next link and the sum total expression of quality is related to the overall linked chain of activities that led to information product. It is *separate* because there are processes related to each link in the chain and efficacy of each process may be assessed for its contribution to a specific quality indicator. Also, in any enterprise, the enterprise may not maintain overall responsibility for every link in the chain. Information may be "customer-supplied products" or "raw materials" provided by another party; information and information components may be supplied externally. Therefore, an enterprise must understand processes for those links in the chain over which they maintain control and understand how information quality is impacted by those links over which they do not have control.

An enterprise may have a single straight forward information quality chain OR the enterprise may have several different and interacting information quality chains. A classic example for USEPA includes links involved in collection, analysis, and reporting of technical measurements. Each potential link in that specific information quality chain and associated processes is summarized below:

TABLE: Information Chain for An Environmental Measurement Project

link	**processes that impact quality**	**associated quality features and characteristics**
planning	location selection data quality objective development data standards development	relevant information acceptable quality objectives standard and comparable data
sample collection	sample identification sample bottle preparation sampling procedures sampling preservation quality control checks	authenticity of sample preserved no contamination, control of quality known, comparable, repeatable procedures sample stability, control of quality control of quality
sample transfer	chain-of-custody maintenance transfer labeling	authenticity of sample authenticity of sample
sample receipt	identification verification chain-of-custody documentation	authenticity of sample authenticity of sample
analysis	preparation procedures analysis procedures QC checks data validation/verification	known, comparable, repeatable procedures known, comparable, repeatable procedures control of quality known and acceptable results

link	processes that impact quality	associated quality features and characteristics
measurement results distribution	electronic data transfer data transfer standards development validation of transfer verification of data usability determination	timely distribution of data consistent and comparable data distribution known and acceptable transfer known and acceptable information content results are usable for their intent
data handling	software actions on data software quality assurance	data remains free of errors
data warehousing	labeling and storage of data	unnecessary duplicates are not in warehouse warehouse data records are complete
data reporting	manipulating data into customer-designated formats	timely distribution of reports usability and format of reports
data accessing	providing data via Internet to the public	timely distribution of data completeness of data usability of data
data archival	storing data when not actively needed	retrieveability of data

Concept 5: Reconciling disparate terminologies

One challenge for USEPA is at the confluence of quality for environmental measurements and quality for information management. Quality managers and information managers need to understand terminology used by each party and to agree on a standard terminology because many words may have conflicting meanings to different parties. Examples include:

TABLE: Disparate terminologies

term	potential meaning in *environmental science*	potential meaning in *information technology*
data	environmental measurement	any representation of a fact
data quality	measurement parameters such as precision, accuracy, representativeness, completeness, comparability	data records are complete
data integrity	potential synonym for “quality”	conformance to technical criteria and business rules
reliable data	data were generated by a reputable source and are of the quality needed	data are correct and have been securely maintained

Quality managers know that there are often multiple definitions for a single term. Attachment one is an example of how terminology may be organized for a quality system which considers environmental and scientific measurements. Each may be useful to quality managers in planning and assessing information quality. The works of both Larry English (English 1999) and Thomas Redman (Redman 1996) were critical resources in developing this list.

Concept 6: Four basic models for information quality systems

Experience is growing in the area of information quality. Quality managers may be able to use one of the information quality models provided in various texts. However, they may, just as likely need to develop their own information quality model by:

- identifying information that is required
- understanding and structuring individual information management system components and other processes which act on information in the information quality value chain
- selecting information quality indicators of interest and measuring them

Quality managers may be confronted with issues regarding the quality of information in any or all of the following four models:

- **Information as an enterprise product -** Some enterprises acquire, develop, manage, process, and sell information as a product of the enterprise. For these enterprises, the process to identify and ensure quality characteristics of their information product resembles a traditional quality system model.

- **Information and information systems which support development of product -** Enterprises may need to access, develop, manage, or process information via information systems to ensure development of the enterprise's products. A great deal of information is created internally. The enterprise may be reliant on the quality of this information to ensure all processes are working as required. In the quality system model, information quality is a distinct portion of the overall enterprise quality system.

- **Information needed to support the quality system -** successful implementation of the enterprise's quality system may be dependent on information generated by the enterprise. For example, measurements made during manufacturing processes may generate quantities of information used to continue quality management for the enterprise. In this quality system model, information quality is a part of the quality management and quality record portion of the quality system.

- **Information quality in communication with potential purchasers and the public -** Increasingly, enterprises are reliant on information and information systems to communicate with purchasers and the public via the Internet, an electronic environment. Quality of information available via this electronic medium may directly impact customers' needs and expectations. In this quality system model, both production and distribution of information are a distinct component in the enterprise's quality system.

Concept 7: Nested quality systems and Russian dolls

Which came first, "the chicken or the egg?" ..... "data or the information system?". This may be a critical question. There are several way to look at "value-added" components of processes that affect data production and information management systems. One useful analogy is to consider quality systems to be "nested," similar to nested Russian dolls. One inside doll could be the quality system for production of environmental measurements data. Another inside doll could be the quality system for production of other data types (e.g., GIS measurements). The outside doll is the quality system for distribution of data via the information management system. Regardless of the outside system, the inside system must still meet quality requirements for its own system. The outside system, can, however, impose some higher level requirements based on higher-level needs.

DEVELOPING AN INFORMATION QUALITY SYSTEM

Quality managers can develop an management system to ensure quality of production and distribution of technical information by the following process:

- Select a standard quality system model (ISO 9001, E4, EPA quality manual chapter 3)
- Identify the information product of the organization
- Assess and determine all individual processes in the information quality value chain
- Identify quality indicators that are valued by customers for information product
- Determine assessment and measurement methodology for those quality indicators
- Apply the quality system model elements including quality policies and procedures in key areas
  - general description
  - quality system overview
  - personnel qualifications and training
  - procurement of items and services
  - documents and records
  - planning
  - implementation of work processes
  - measurement
  - assessment
  - quality improvement

Select a standard quality system model

Some standard quality system models are available for use in establishing an organization-wide information quality system. EPA's 5350.1 A1 Chapter 3 provides guidance for individual elements that may be considered in a quality system. Part A: Management System of American National Standard, ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.* Part is based on general quality system elements expressed in the ISO 9000 standard. The model for E4 is also useful because it proposes and general management system and then provided a focus on separate technical areas. Additional areas may need to be added for each individual user.

Identify information product of the enterprise

Determine to what extent information is an enterprise's product. Are there types of information? Who are the customers? What is information used for? How is information developed? What is the relation of information product to other enterprise products?

Assess and determine all individual processes in the information quality value chain

Chart out each type of information using an information quality value chain. Identify individual processes that create or act on information at each step in the process. Are there standard operating procedures for these processes? Are there already process controls in place for these processes? Do you understand the relationship of these processes to the quality of the information? Document the results. Be sure to clearly express the relationship between production (developing, observing, and recording data) and distribution (receipt, processing, warehousing, and reporting) aspects.

Identify quality indicators valued by customers

Identify customers for information product, both external customers and those who may be considered to be "internal" users of information. Have they identified information as a product? Do they have expectations for the information? Do they have written requirements for production or distribution of information? Are known quality indicators well defined? Document the information quality indicators and write formal definitions for each indicator and relate them directly to processes identified in the previous section.

Determine assessment and measurement methodology for quality indicators

Review the information quality indicators and evaluate the need for measurement methodology. Has the customer already detailed a specific measurement methodology? Is there more than one way to measure for each information quality indicator? Has the customer already expressed minimum acceptance criteria for information? Have baseline measure already been established? Has anyone already been tracking conformance to any information quality measures against other variables such as time? Is terminology for measurement consistent among all users? Document the results.

Develop a written management system for information quality

Plan out the contents of the written management system for information quality. One useful approach is to develop the system using a three-tiered approach based on the ISO 9001 model.

THREE-TIERED MODEL

The following three tiers are suggested for an information quality management system model:

Top tier - vision, mission, and general description of the information quality system

Record the mission and vision of the enterprise. Develop a written statement of enterprise-wide quality policy which captures the overall emphasis on the quality system by management. Develop a general description of the quality system which identifies key elements for planning implementation and assessment. Include in this level tables which detail quality system commitments in the following areas:

- **roles and responsibilities** - identification of management and quality management roles cross-referenced to activities critical to quality system development (resource commitment, quality system records, assessment schedule, training, quality records, procurement, etc.)

- **quality system records** - record type (quality plan, quality reports, etc.) cross-referenced to responsibilities for preparation, review, approval, frequency of development, and distribution

- **quality assessment schedule** - assessment types (e.g., project, product, system, quality system, data system, etc.) cross-referenced to assessment tool, assessors, basis for assessment, minimum frequency, purposes for assessment, and review authority

Tier two - organization-level quality policies and procedures

Develop individual statements of quality policy for each key area of the information quality system and include higher level procedures. This approach will allow for future editing to the overall quality manual for a single quality area without re-drafting the entire overall document. For each individual quality policy, include the following elements at a minimum:

- policy title
- approval authority and date
- succinct policy statement
- individual statement of quality requirements (if greater detail is needed)
- purpose
- scope
- responsibility and the role for implementing that responsibility
- listing of any associated documents
- procedures
- quality control (checklist) items that must be addressed

Inclusion of the checklist will encourage quality managers and staff to not develop any specific policies and procedures that are not planned to be implemented.

The types of specific quality policies and procedures that may be most useful in an information quality system include:

- **general quality system "housekeeping"** - quality documents, quality records, quality system roles and responsibilities implementation, quality system dispute resolution, quality system improvement
- **quality support operations** - standard operating procedures format and development protocols, quality and other technical training processes, customer satisfaction surveys
- **identification of quality indicators -** information production indicators, information distribution indicators, technical information indicators, measurement methodology, measurement methodology development (both production and distribution criteria)
- **information production, project and program planning requirements** - customized requirements for planning each kind of information production product including objective development, acceptance criteria, and ensuring appropriate quality indicators related to information distribution are also addressed where appropriate
- **information distribution, project and program planning requirements** - customized requirements for planning each kind of information distribution product including, objective development, acceptance criteria, and ensuring appropriate quality indicators related to information production are also addressed where appropriate
- **information and data warehouse maintenance planning requirements -** requirements for ongoing maintenance and operation of a large database system including responsibilities for data stewardship and routine monitoring and reporting of applicable quality indicators
- **information security** - minimum requirements for monitoring and maintenance of information security
- **assessment procedures** - processes for assessing information products, processes, systems, database systems, developing assessment schedules, corrective action in response to assessments

Tier three - standard operating procedures

Tier three consists of the individual SOPs of the enterprise or each unit in the enterprise. SOPs are the actual work instructions for performing individual activities and are subject to frequent change. SOPs should be written in a way which facilitates their use and each modification for improvement.

The EPA Office of Environmental Information developed a *Management System for Quality* which details both level one and level two as described above. OEI is working to implement the system and develop requisite SOPs. Electronic copies of OEI's new quality system (and this technical paper) can be obtained by sending an Email request to the author (Worthington.Jeffrey@epa.gov).

CONCLUSION

USEPA and other Federal Agencies are actively unifying and integrating disparate information systems. As businesses and more government operations increase reliance on these centralized and standard information systems, the quality manager's job will be easier. Understanding the nature of the quality of the information and how information processes may act on the quality of the information will remain key to the ability of the quality manager to develop useful measurement tools for managers.

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USEPA information resources available on the web: www.epa.gov/oei

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ATTACHMENT ONE
INFORMATION QUALITY AND DATA QUALITY DEFINITIONS

The following definitions may be useful for discussion or reference when developing an integrated quality system to support production and distribution of technical information.

DATA DEFINITIONS

datum - (data item) is a *representative triple* which consists of **e, a, v** where

> **e** = entity (and entity's meaning)
> **a** = attribute (and attribute's meaning)
> **v** = value (and value's meaning) Value may include *units* when the datum represents a measurement. (Redman 1996)
>
> NOTES
> a. The datum represents some element in a model; the element is a real world thing (tangible = physical, intangible = e.g., idea) or event. As an event, the datum would need to be captured at the point of the event.
> b. The datum usually represents a fact, a truth, or observation about the real world; but does not always have to represent a fact.

data representation - a set of rules for recording data (*representative triples*) on some medium

> NOTES
> a. Therefore, the same data may be represented in different ways.
> b. Therefore, data represented in a prescribed manner may be recorded many times.
> c. Data can exist without being represented.
> d. These rules are a form of "metadata" (Redman 1996)

data record - a physical instance standing for a set of data items according to the data representation

> NOTES
> a. Data can exist without being recorded. (Redman 1996)

environmental data - data of measurements or observations that describe environmental processes or conditions, or the performance of environmental technology (ANSI/ASQC E4-1994)

> NOTE: In a broader sense, these data may include ancillary data which are needed so that the data have meaning (are useful as *information*), data such as: name of the sample site, sample location, sample no., collection methodology, etc.

geospatial data - data of geospatial measures that include a three-dimensional reference system (usually based on a model of the real world)

> NOTE: Often the three-dimensional reference system is cross-referenced to observational data regarding a physical attribute for locations and if often considered to be *environmental data.*

quality indicator data - data of the quality indicators.

> NOTES:
> 1. When associated with environmental measurements, this data is usually developed and recorded at the same time the measurements are developed and recorded.
> 2. This type of data is sometimes referenced as *meta-data.*

INFORMATION DEFINITIONS

information - a datum or data presented to meet customer expectations

NOTES:

a. Data presentation must be "knowledge worker-friendly."

b. Data presentation must impart meaning to the data.

information production - that aspect of the information which is associated with the creating, updating, collecting and storing information that gives the information value to the stakeholder (vs. other aspects of the information such as the *data representation*)

information distribution - that aspect of information that is associated with the distribution (i.e., extraction, manipulation, and presentation) of information.

information system - in the broadest sense, a system of functions concerning the acquisition and transfer of information. (Principia Cybernetica 2000)

NOTES:

a. Carriers in an information system can be biological, social, or personal units, etc.

b. An information system is dedicated to a certain type of information (e.g., environmental information.

c. A storage device is usually part of an information system.

QUALITY AND *SYSTEMS* DEFINITIONS

quality - the totality of *features* and *characteristics* of a product or service that bear on its ability to meet the stated or implied needs and expectations of the customer.(ANSI/ASQC E4-1994)

quality assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.(ANSI/ASQC E4-1994)

quality control - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that the meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.(ANSI/ASQC E4-1994)

quality feature - an individual feature of a product or service that is identified as a feature of interest for the purpose of a quality system.

NOTE: A quality feature may be subject to measurement (see *quality indicator)*.

quality indicators - measurable attributes of the attainment of the necessary quality (quality features).(ANSI/ASQC E4-1994)

NOTE: In USEPA, quality indicators originally were applied solely to the "quality necessary for a particular environmental decision and included: *precision, bias, completeness, representativeness, reproducibility, comparability,* and *statistical confidence*. OEI in identifying a greater breadth of quality indicators to describe and measure the quality of overall Agency information quality.

quality management - that aspect of the overall management system of the enterprise that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, assessment) pertaining to the quality system.(ANSI/ASQC E4-1994)

quality system - *"the management system for quality"* a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an enterprise for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, assessing work performed by the enterprise and for carrying out required QA and QC.(ANSI/ASQC E4-1994)

management system - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an enterprise for conducting work and producing items and services.(ANSI/ASQC E4-1994)

DATA QUALITY DEFINITIONS

data quality - the totality of features and characteristics of data that bear on its ability to meet the stated or implied needs and expectations of the customer.

NOTE: One narrow definition of data quality is

"data quality = data representation quality + data record quality"

data representation quality - attributes of data representation quality include:

- the rules for recording data provide data meet the customers' definition
- the format allows for processing by explicit procedures
- the format allows data to retain its characteristics during repeated use

data record quality - attributes of data record quality include:

- the record is a true record of the element that was meant to be recorded (special cause bias)
- the record was accurately recorded (freedom from common cause bias; e.g., systematic data entry error)

data standards quality - the degree to which the data standards enable people to easily define data completely, consistently, accurately, and understandably. (English 1999)

data architecture quality - the degree to which the data models are reused, stable, and flexible and how well they depict the data requirements of the enterprise; and how well the databases implement those requirements and enable capture, maintenance, and dissemination of the data among the information customers. (English 1999)

INFORMATION QUALITY DEFINITIONS

information quality - the quality of the information production + the quality of the information distribution (see following sections)

INFORMATION PRODUCTION QUALITY DEFINITIONS

information production quality - the totality of features and characteristics of information production that bear on its ability to meet the stated or implied needs and expectations of the customer.

(**environmental) measurement quality** - the quality indicators that describe the (inherent) quality of environmental measurement results. These include *precision, bias, completeness, representativeness, reproducibility, comparability,* and *statistical confidence*.

information verification and validation - the degree to which the information has been verified and validated and show to meet requirements related to development of the data (e.g., analytical methods validation)

INFORMATION DISTRIBUTION QUALITY DEFINITIONS

information distribution quality - the totality of features and characteristics of information distribution that bear on its ability to meet the stated or implied needs and expectations of the customer. (e.g., *data entry quality, data warehouse quality, information architecture quality*, etc.)

date entry quality - those quality features that describe quality related to the data entry process (e.g., *correctness, completeness, data entry verification, data entry validation*)

data warehouse quality - those quality features that describe the quality of data resident in Agency data warehouses (e.g., *duplicate data entry, completeness*)

information architecture quality - the degree to which information models are reused, stable, and flexible and how well they depict the information requirements of the enterprise (e.g. *non-redundant system processes, business information model clarity, operational data model clarity*) (English 1999)

software quality - those quality features of the software that ensure that the software meets the data and operational requirements of the stakeholders and ensures the quality of the information managed and delivered by the software. (e.g., *verified software, validated software, conformance of software to enterprise requirements*)

hardware quality - those quality features of the hardware that ensure that the hardware meets the requirements of the stakeholders and ensures the quality of the information managed and delivered by the hardware (e.g., *reliability, maintainability*)

information usability - the degree to which information is usable for its intended purposes.

HOW GOOD ARE MY DATA?: INFORMATION QUALITY ASSESSMENT METHODOLOGY

Jeff Worthington, USEPA, Office of Environmental Information
George M. Brilis, MBA, JD, USEPA Office of Research and Development

Abstract — Quality assurance techniques used in software development and hardware maintenance/reliability help ensure that data in a computerized information management system are maintained well. However, information workers may not know the quality of data resident in their information systems.

Knowledge of the quality of information and data in an enterprise provides managers with important facts for managing and improving the processes which impact information quality. This paper provides information to assist information workers in planning and implementing effective assessment of information data and quality. The areas covered here include:

- *identifying appropriate information quality indicators*
- *developing assessment procedures*
- *conducting information quality assessments*
- *reporting information assessment results*
- *tracking improvements in information quality*

KEY WORDS: information quality, measurement, database

BACKGROUND

The source of information and data that may be of value to a customer may not be directly known, may be unreliable, or may need to be checked for verification purposes. Also, data and information may be old and there may be reasons to doubt its reliability. Alternatively, processes in use when data and information were developed may not be understood in relationship to the quality of the information and data themselves. Other questions about the veracity of the information and data may be of interest to a customer and therefore, a quality concern. For example:

- to what degree are two disparate databases comparable?
- is the quality of the data affected by transfer into a new system?
- am I getting my data fast enough?

Many quality systems focus primarily on data *production*. For example, in the USEPA, the quality system considers production of environmental measurements and recording resulting data and quality indicators (AKA, metadata). In software development, software quality systems may only consider writing consistent code and the valid operation of the system according to identified data requirements and system requirements. However, for information and data themselves, quality may not always be known.

For quality managers to assist enterprise management in systematic planning and improvement of information and data quality, quality managers must have the ability to assess all aspects of data and information quality. Even though, assessment capability alone cannot replace implementation of a robust quality system, it is a critical feature in a quality system and is an important tool in understanding the current status of information and data quality.

The following provides a discussion of the types of information quality assessments that quality managers may consider. Assessment planning, assessment scope development, and assessment implementation are also discussed.

TYPES OF INFORMATION QUALITY ASSESSMENTS

There are several ways to consider types of information quality assessments.
For example, one way is to look at the product-process-system trilogy:

- **information/data product** - the end product of all the processes
- **information/data process** - an individual process in production or distribution of data or information
- **information/data system** - the entire collection of processes which make up the system

Information/data product assessments

Assessment of information/data products evaluates conformance of product to customers' expectations. The expectations may be expressed as quality indicators and include a basic measure of correctness.

Information/data process assessments

Assessment of information/data processes evaluate process effectiveness and process impact on quality of the information/data product.

Information/data system assessments

Assessment of information/data systems evaluate all aspects of the management system and technical system to evaluate system effectiveness for achieving intended results. This level assessment may also focus on conformance to an industry-wide, external, or other standard specifications.

In addition to the above scope approach, assessments can also be objective-based. The following are some examples of some objective-based information quality assessments:

- **external data quality** - quality of all information/data provided by an external provider
- **pre-award assessment** - preliminary assessment of a supplier's information quality system
- **data element assessment** - quality of data element definition for all data elements of a certain type
- **individual quality indicator assessment** - assessment of an individual quality indicator such as timeliness or the delivery of all information
- **conformance assessment** - conformance to an external standard

INFORMATION/DATA PRODUCT ASSESSMENT EXAMPLE

For the purposes of brevity, this technical paper addresses a single example of the process that might be employed for assessing information/data product. The paper also explores the potential relationship of the end result of the assessment to the information/data processes and system that produced the product. The example product considered here is a large database maintained by an enterprise for a long period.

PRE-ASSESSMENT PLANNING

The assessor needs to carefully plan the assessment in advance in order to perform an efficient and effective assessment. In some cases, the assessor may be able to perform the assessment within an electronic environment and not need to travel to a separate location. This is most likely when the assessment involves quality of data in one or more databases. In those situations where the process or system must be looked at, the assessor will most likely need to visit the site and people involved in the processes and overall system.

Determine purpose and scope of the assessment

The assessor should meet with customer or management representatives and determine the purpose and scope of the assessment. How assessment results assessment may be used is critical in planning the assessment. Collecting assessment information that has no use is a waste of resources. For a database assessment, assessment scope is based on:

- amount of data in the system
- quality indicators that are of interest to the customer

Assessment results often need to be the subject of corrective actions and planning for future preventative actions. If that is the case, the process by which the assessor identifies nonconformances and defects and how the corrective action process will be implemented must be discussed in advance. Assessors may be involved in follow-up review of a written corrective action plan or even the revised information/data product itself. It is critical to establish this process prior to conducting the assessment.

Identify applicable information quality indicators

Customers for the product, process, or system have needs and expectations for data and information which are produced and distributed. Meeting with the customers for the data allows the assessor to identify information quality indicators valued by the customer. Attachment 1 identified some potential information quality indicators. Alternatively, if the person/group who requested the assessment has a robust information quality management system, that system may be a good resource for identifying information quality indicators.

Establish measurement methodology

Once quality indicators are selected, the measure of the quality indicator must be determined. There may be more that one possible measure for a single quality indicator. A good example of this is in the case of **timeliness,** which is expressed as two forms of **information float:**

- **information float 1** - the time it takes for an item of information to be collected into a data system form the time the information was first available

- **information float 2** - the time it takes for an item of information to be available to a system user from the time it is first collected into the data system

For either type of information float, there are at least two possible measures:

- **time units** - a direct measure of time (e.g., days, hours, minutes, seconds)

- **conformance** - a measure if the information was received in time for its use (e.g., yes or no)

Statistical sampling
Selecting a sample of the overall data population may be necessary to evaluate an individual quality indicator. Sampling methodologies include (English, 1999):

- **random sampling** - use of random number generator to provide equal chance to select every item of data
- **systematic sampling** - selection of every nth record, based on ration of required sample size to total population (for use when data records are already random)
- **stratified sampling** - when there is more than one stratum in the records, to ensure the selection of adequate records in each strata
- **cluster sampling** - selection of subsamples from logical clusters in the database and combining them

Determine the need for acceptability criteria
Depending on the scope of the assessment and maturity of the quality system in place for information and data, the assessor may need to establish acceptability criteria to report any measurement as a nonconformance.

When sample methodology is employed, acceptability criteria form the basis for the determination of sample size based on the desired confidence level. Larry English provides a detailed explanation of the applicability of acceptance sampling methodology is his recent book (English, 1999).

Identify alternative information source
For some quality indicators (e.g., **accuracy to original data**), assessment of information quality may require identification of an alternative or additional information source to use as the basis for comparison. Identify those sources prior to the assessment, if possible, and verify with the customer for the assessment the authenticity/acceptability of the alternative information source.

ASSESSMENT WORKING PAPERS
The assessor should develop documents which serve as the basis of the assessment and facilitate the recording of both observations and conclusions. This approach is consistent with all assessments.

Assessment plan
The assessment plan need not be long, but it should be documented and should include:

- assessment identifier (number)
- type of assessment
- scope of assessment
- purpose of assessment
- proposed assessment data
- proposed assessors (phone/address)
- location of assessment
- selected assessment target areas
- contact persons

Assessment standard operating procedures (SOPs)
Assessors may need access and training in standard operating procedures for the purpose of conducting routine and consistent assessments. These SOPs should include details in measurement methodology for information/data quality.

Assessment requirements
The assessors may benefit from developing a list of assessment requirements based on their own expertise and the customer’s needs for the assessment. This list of assessment requirements helps focus assessment planning, checklist development of the checklist, and assessment conduct.

Assessment checklist
Assessors need to develop an assessment checklist to serve as a reminder of all the areas that the assessors intent to cover in their assessment of the database. This checklist also then becomes a formal record of the assessment in combination with whatever electronic records are created in the process.

Notification and request for information letter/memorandum
Prior to the conduct of the assessment, the assessors should formally provide notification of the assessment in a letter or memorandum. The letter should include the assessment plan. One option is to include the assessment checklist to allow the persons responsible for the data an opportunity to prepare for the assessment.

Reporting format
Assessors will need a standard reporting format for communicating the results of the assessment. The structure of this reporting format should reflect the planning for the corrective action process. The most important feature of the report is to ensure that the assessors can easily develop this report so that no time is lost in reporting the assessment. The later that assessment results are provided, the less impact and credibility of the assessment process. One method to ensure rapid reporting is to severely limit the approval process. A well-organized assessment system should empower the assessor to produce a final report with no management review.

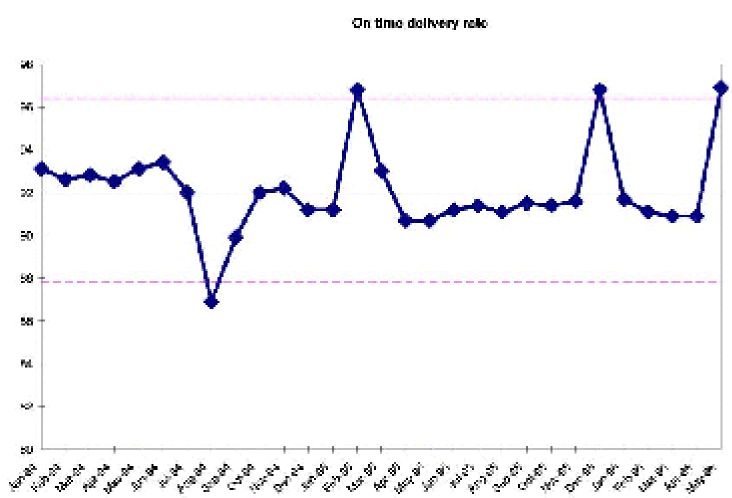
CONDUCTING THE ASSESSMENT
Communication during the entire process of assessment in crucial in garnering support during the process and in effective utilization of assessment results.

Pre-assessment briefing
Meet with the parties that are responsible for the database, go over the audit plan carefully explaining the purpose and scope, assessment methodology, and ask if there are any questions. This is a good time to work out last minute details, such as concerns about access to data and how assessment results night be received. Be sure to go over in detail any corrective action processes that were planned.

Assessment implementation
Make a record of all electronic processes used in the assessment process and, if possible, provide a printout and electronic file of any nonconformances identified in the information under review.

Assessment debriefing
At the conclusion of the assessment, be sure to provide the persons responsible for the data and information with a personal debriefing of the findings of the assessment. Discussion of the corrective actions as well as preventative actions that can be implemented immediately may be helpful.

CORRECTIVE ACTION IMPLEMENTATION



Planning actions to correct identified problems with information quality can be a meaningless exercise and a waste of resources unless there is a process to ensure implementation of the planning. Verification by assessors is useful; however, this approach places the burden of verification on the assessors and requires additional resources to perform the verification. The corrective action process should be a standard process of the enterprise that is assessed, and the process must provide some form of verification for each type of finding reported in an assessment.

PREVENTATIVE ACTIONS

Establishing preventative actions processes will ensure improvement in the quality of the information and reduce reliance on the assessment process to determine and monitor the quality of the information.

ASSESSMENT RESULTS IN ONGOING QUALITY SYSTEM MONITORING

An important use of the results of information quality assessments is for ongoing monitoring operations. For certain information quality indicators, quality managers can routinely monitor the quality of the information in the form of a **control chart**. For example, the number of defects in information received from an outside parts may be a variable subject to measurement. Ongoing measurement and charting of the number of defects will allow the quality manager to calculate upper and lower control limits. Using this information, the quality manager can examine the processes used to develop the information that is being assessed and determine if improvements to the process actually result in increased quality.

COMMENTS ON MEASUREMENTS

Users of technical information resident in computer systems need to pay special attention to the issue of measuring data quality because the technical information in many cases consists of measurement data. Measurement data includes quality indicators which provide useful information regarding the measurement in terms of the accuracy, bias (precision), representativeness, completeness, comparability, and sensitivity of measurement methodology used.

Both technical measurement results and associated quality indicators are subject to quality concerns related to *distribution* of data, because once recorded in the electronic environment, they are essentially equivalent data elements. Assessment of information quality for *distribution* processes, is also a measurement process. Development of measurement methodology, acceptance criteria, sampling techniques, and confidence intervals result in similar quality indicators for information *distribution.* For example, accuracy and precision of a measurement process to determine the number of defects in a database are important indicators of the efficacy of the quality measurement.

Assessors must be able to clearly explain the unique nature of the categorization of various types of measurement quality indicators so they can communicate quality system needs, assessment results, and opportunities for improvement without confusion.

CONCLUSION

Quality managers can apply existing assessment methodologies to all quality aspects of technical information held as data in information systems. A well operated and consistent assessment process will provide valuable tools for managers to know and improve the quality of their information. Identifying usable quality indicators, measures for those quality indicators, and acceptance criteria is an important process for planning assessment. Establishing and communicating the relationships of these indicators to specific processes for both production and distribution of information will facilitate development of quality improvement approaches.

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http://www.thedecalogue.com/cchartq2.htm - control chart graphic

INFORMATION QUALITY INDICATORS FEATURES MATRIX

TYPE	QUALITY FEATURE	QUALITY INDICATOR	DEFINITION	MEASURE
DATA	data representation	data representativeness	a measure of the degree to which the set of rules for recording data meet the needs of the user	% or Y/N
		data rep. completeness	a measure of the degree to which the set of rules for recording data ensure data are completely represented	% or Y/N
		data rep. documented	a determination if adequate documentation of the data representation is provided	% or Y/N
		data rep. granularity	a measure of the degree to which the rules for recording the data provide for recording the correct amount of granularity	% or Y/N
		data rep. validity to business rule	a measure of the degree to which the rules for recording the data are a valid representation of the associated business rules	% or Y/N
		data name	the degree to which the data name, entity name, attribute name clearly communicate the meaning of the objects named (English, 1999)	% or Y/N
		data name consistency	the degree to which the data and entity names are consistent across all presentation media, such as field names, screens, reports	% or Y/N
	data record	data record accuracy to surrogate	a measure of the agreement of the data record with the information record on a surrogate (such as a field sheet or survey form)	% or Y/N
		data record accuracy to reality	a measure of the agreement of the data record with the data source	% or Y/N
		data record business rule conformance	a measures of the conformance of data values to its domain and business rules	% or Y/N
		data record timeliness (information float 1a)	a measure of time for the data record to be made and for the data record to be placed in a formal data base system	time (days, hours, minutes, etc.)
		data record timeliness (information float 1b)	the measure of failures to accomplish the enterprise’s goal(s) because the data record was not available to the data system when needed	failure rate
	data standard	data standards	the degree to which the data standards enable people to easily define data completely, consistently, accurately, and understandably	Y/N

TYPE	QUALITY FEATURE	QUALITY INDICATOR	DEFINITION	MEASURE
INFORMATION CONTENT	scientific measures	measurement precision (meas. accuracy 1)	a measure of mutual agreement among individual measurements of the same property (usually under prescribed similar conditions)	standard deviation
		measurement bias (meas. accuracy 2)	a systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected measurement is different that the sample's true value)	numerical difference between expected and true value
		measurement representativeness	a measure of the degree to which results (data) accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition (ANSI/ASQC E4-1994)	
		measurement completeness	a measure of the amount of valid results (data) obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions. (ANSI/ASQC E4-1994)	
		measurement comparability	a measure of the confidence with which one set of environmental measurement results (a data set) can be compared to another (ANSI/ASQC E4-1994)	
		measurement reproducibility	a measure of the reproducibility of a measurement methodology	
		measurement verification	a measure of the verification that a measurement was assessed to process requirements	
		measurement validation	a measure of the validation of a measurement to results requirements	
		measurement usability	an assessment of a measurement for conformance to use requirements	
		measurement documentation	measurement was adequately documented	
	geospatial measures	to be determined		
		to be determined		
		NOTE: May include quality indicators for scientific measures above.		
	survey measures	to be determined		
		to be determined		
		NOTE: May include quality indicators for scientific measures above.		

TYPE	QUALITY FEATURE	QUALITY INDICATOR	DEFINITION	MEASURE
	administrative data	conformance to the enterprise's business rule	the degree to which the data conform to all the business rules and administrative requirement of the organization	% or Y/N
	financial data	correct classification	financial data are recorded in the correct classification	% or Y/N
	system meta-data	system meta-data completeness	the degree to which meta-data are complete	%
		system meta-data business rule conformance	a measure of the conformance of meta-data to the business rules	% or Y/N
INFORMATION DELIVERY	data collection and input	data entry freedom from defect	a measure of the correctness in the data entry of information	%
		data verification	the degree to which data were verified to meet process requirements	%
		data validation	the degree to which data were validated to meet output requirements	%
	operations, analysis, software	verification of software	a measure of the degree to which software are verified	% or Y/N
		validation of software	a measure of the degree to which soft ware are validated	% or Y/N
		conformance of software to enterprise requirements	a measure of the degree to which software conform to the requirements of the enterprise	% or Y/N
		efficiency in software operations	a measure of the use of resources compared to the scope and complexity of the assignment	% or Y/N
	architecture *architecture conformance to enterprise information requirements*	redundant system processes	a measure of the redundancy of unnecessary system processes	%
		business information model clarity	a measure of the clarity of the business information model (does it provide all the information needed in a clear manner) (English, 1999)	Y/N
		operational data model clarity	a measure of the clarity of the operations data model (stable, flexible, clear, complete)	Y/N
		distributed database architecture and design	the degree to which the processes control the physical distribution of database data	Y/N

TYPE	QUALITY FEATURE	QUALITY INDICATOR	DEFINITION	MEASURE
	facility, hardware	facility security		
		facility conformance to hardware requirements	a measure of conformance of the facility to hardware requirements (and enterprise requirements)	Y/N
		hardware conformance to enterprise needs	a measure of the conformance of hardware to enterprise requirements	Y/N
		reliability of hardware	a measure of the reliability of the hardware	failure rate, etc.
		hardware maintainability	a measure of the resources needed to maintain hardware	money or resources
	output/reports (data warehouse)	data report availability	a measure of the availability of reports on data from a data system	% or Y/N
		data report contextual clarity	a measure of the degree to which data presentation enables the information customer to understand the meaning of the data and avoid misinterpretation (English, 1999)	%
	Internet/cyber	web information availability	a measure of the availability of information that is needed by the information customer (see GOAL 7)	% or Y/N
		web information accessibility	a measure of accessibility of information that is needed by the information customer (see GOAL 7)	% or Y/N
		page loading speed	the time it takes for individual pages to fully load at a “normal” work station (Tamini, 2000)	time
		contact information visibility	the presence/absence of contact points if the information customer needs additional information or has a question (Tamini, 2000)	% or Y/N
		timeliness	the amount of time from when information (e.g., environmental data) is available to an organization until it is available to information customers who use the information at the web site (Tamini, 2000)	time
		functionality of links	a measure of the degree to which there are inactive links in a web site (Tamini, 2000)	% or Y/N
		spelling, clarity, organization	a measure of the “readability” of the information provided at a web site	Y/N (potentially subjective)
		web site modification timeliness	the amount of time from when changes need to be made to reflect organization changes (e.g.,re-organization, changes in programs, etc.) and the time the changes are made to the web pages this is the amount of time incorrect information is being provided to information customers	time

TYPE	QUALITY FEATURE	QUALITY INDICATOR	DEFINITION	MEASURE
DATA WAREHOUSE	data architecture	data relationship correctness	the degree to which relationships among the real-world objects is correctly represented by the data - *entity type* to *entity type* - *attribute* to *entity type* - *entity type* to *entity subtype*	% or Y/N
	storage	duplicate database records	a measure of the number of incidents of duplicate data entry in a single database	%
		unnecessary multiple data representation	a measure of the number of incidents where data are unnecessarily entered in more that one data representation	%
		redundant storage of system data records	a measure of the agreement of data when data are necessarily entered into redundant storage	
		data report potential accessibility	the degree to which all potential data needed by the enterprise for information customers are accessible (English, 1999)	%
		data report actual accessibility	to degree to which the data that are accessible to information customers can be actually accessed (i.e., ease of use) (English, 1999)	%
	archiving	archival timeliness	the degree to which data are placed in archival according to enterprise requirements	time or %
INFORMATION COSTS	process failure costs	irrecoverable costs	costs which are not subject to recovery (such as mailing notification letters to the wrong person) (English, 1999)	
		liability and exposure costs	actual costs and potential risks (such as the liability potential if incorrect information is used to make a decision) (English, 1999)	
		recovery costs of unhappy users	the compensation costs and resource costs to fix a problem because of poor information quality (English, 1999)	
	information scrap and rework	redundant data handling and support costs	the costs of developing and maintaining alternative data systems to handle the same data because the information customer cannot use the data in the first database system (English, 1999)	
		costs of hunting or chasing missing information	the costs of finding missing information, lost productivity because those resources were searching for information, and the cost of doing “rework” correcting the problem (English, 1999)	

TYPE	QUALITY FEATURE	QUALITY INDICATOR	DEFINITION	MEASURE
		business rework costs	the costs of re-performing processes that failed, such as reprinting reports because the first report generation efforts failed (English, 1999)	
		workaround costs and decreased productivity	the costs of performing alternative work, when poor quality information prevents preforming the normal process, such as completing administrative documents manually when the software fails to work (English, 1999)	
		data verification costs	the costs to the information customers of performing additional manual “quality inspections” to verify the quality of the information because they do not trust the quality (English, 1999)	
		software rewrite costs	the costs to fix application programs when they fail, recover form the problems caused, and rerun the programs (English, 1999)	
		data cleansing and correction costs	the costs of data cleansing (which are usually waste costs because they would often be unnecessary if the information was correctly created and maintained)	
		data cleansing costs	the costs of software to cleanse data from a source database (English, 1999)	

Data Standards are Back Seat Drivers! Methodology for Incorporating Information Quality into Quality Assurance Project Plans

Lora Johnson, USEPA National Exposure Research Laboratory
Jeffrey C. Worthington, USEPA Office of Environmental Information

Abstract: Quality assurance project plans for environmental data collections consider user requirements for the measurements and express these in the form of data quality objectives. User requirements now may include capture of measurements and associated information in prescribed formats to facilitate entry into computerized information systems. Establishing ahead of time that the data requirements may be an important "back seat driver" for an environmental collection effort can save considerable resources for an organization. Also, the planning may need to accommodate unique requirements associated with the entry of data into data collection systems.

INTRODUCTION

EPA's requirement for quality assurance project plans is well recognized by professionals working in the environmental arena. Two Agency documents typically guide the development of QAPPs:

- EPA Requirements for Project Plans (QA/R-5)
- Guidance on Quality Assurance Project Plans (G-5).

These two documents appropriately focus on the how, when, where, why, and who of project logistics but typically do not deal with information management issues beyond the immediate use of the data for decision making purposes. As the Agency adapts to conducting business in the "information age," project information and results are more often viewed as a strategic resource to be managed beyond the needs of the first user of the data. In order to manage the information resource so that it retains integrity, is retrievable, and can be readily understood, information quality issues must be considered on a parallel track with all other project planning activities.

BACKGROUND

In 1980, when EPA issued the first guidance for writing QA project plans, the focus was on providing data of adequate and documented quality by controlling field sampling logistics and laboratory chemical analyses. Data were collected with a one-time, specific purpose in mind and project records were stored in filing cabinets accessible only to those who had immediate knowledge of that the records existed. A typical use of computer technology was to manually enter data into a mainframe computer for subsequent interpretation with a statistics package like SAS. The state of computer technology did not yet mandate that QA/QC activities also clearly focus on information quality.

By the 1990's, as part of the Administration's efforts to reinvent Federal government, EPA was focusing on public access to major Agency data sets and electronic reporting of compliance data. Progress on these and other initiatives was slow and difficult because little in the way of an information management infrastructure existed. The Office of Environmental Information (OEI) was established to rectify this situation and is tasked with providing for the efficient transmission, storage, and retrieval of Agency information.

One of OEI's functions is to establish data standards. A data standard is a statement of the specific rules governing the recording of information so data are meaningful and useful. A data standard insures data are recorded without ambiguity (i.e., EPA Chemical Data Standard). Data standards also facilitate sharing information among computers because data are recorded in a standardized format (e.g., yyyymmdd vs ddmmyyyy). Although EPA had attempted to establish data standards through one of OEI's predecessor organizations, as far back as 1987, little progress was made given that each EPA program and project independently designed their own data bases.

To date, the quality assurance process has emphasized planning and implementation because the only customers identified were those who might immediately use the data. Now the long-term storage and sharing of project information must also be considered because there are now additional customers that need to be considered, the public and other interested information workers. Quality professionals can accommodate the diverse needs of this wider customer group by following the QA project planning process and relying on Agency data standards as described below.

A Quality Planning Approach that Combines Measurement Quality with Information Quality

The following is a suggested approach to preparing a QA project plan that can benefit from a consideration of data standards.

Step 1 **Will the plan describe work that will likely become a part of EPA's institutional memory?**
Will it support regulation development?
Will it provide environmental measurement data for status and trends use?
Is it a site remediation project?
Is it a highly visible project?
Will it support methods development?

Step 2 **Examine the current listing of Agency data standards at:**
http://oaspub.epa.gov/edr/EPASTD$.STARTUP
Select those that are relevant. A listing from 3/1/00 is provided in Table 1.
Plan data collection to capture all the data elements in the relevant data standards.

Step 3 **Insure data management is controlled during the implementation phase of the project.**
Designate a "data steward" during project implementation.
Submit data to the data steward as real time as possible.

Use standard reporting formats.
Check the data as it is returned.

Step 4 **Insure data are reviewed at each step of the project**
Identify any step where data are transferred (hard copy to hard copy, hard copy to computer, computer to computer).
Develop checks to insure data integrity are maintained.

Step 5 **Select an Agency supported data architecture**
Consider the use of STORET (http://www.epa.gov/storet/)
and EIMS (http://www.epa.gov/eims/eims.html)
Assign a new data steward if necessary

Step 6 **Plan for public access**
A data steward can answer questions or direct them to appropriate subject matter experts.
Characterize the quality of the information. See Table 2 for suggestions.

THE FUTURE

The quality assurance project plan is a readily available tool for improving information quality. By simply incorporating appropriate data standards into the planning phase of the project, critically important measurements and associated information can be readily identified. The benefits are immediate to the project: plans for handling data transmission, verification, validation, and storage can be made. Long term benefits include data comparability, integrity, and reuse. The days of struggling to interpret the meaning of lone numbers with inadequate metadata will give way to a more efficient and effortless system of information management.

Table 1. EPA Data Standards (3/1/01)

NAME	STATUS
Biological Taxonomy	Final
Chemical Identification	Final
Latitude/Longitude	Final
Date	Final
SIC/NAICS	Final
Facility Identification	Final
Tribal Identifiers	Under Development

Geospatial Referencing	Under Development
Permitting	Under Development
Enforcement/Compliance	Under Development

Table 2 Information Quality Indicators

QUALITY INDICATOR	**DESCRIPTION**
measurement results quality completeness	the degree to which quality information needed to describe the quality of the measurement results is available for customers
database comparability	the degree to which measurement results recorded in the database are comparable to results in other databases of interest
data security	verification that the data are free from intentional and unintentional access by unauthorized users
data system integrity	the degree to which the data system conforms to technical criteria and business rules
data standard conformance	the degree to which data system elements conform to required data standards
data system usability	a measure of the usability of the data system based on customers' expectations
data system access	a measure of the ease of access to data content based on customers' expectations
data duplicate	a measure of the unnecessary duplication of records within a single data system
non-required multiple data entry	a measure of the recording of redundant information in different formats (because no data standard is set or used)
agreement of intentionally redundant records	a measure of the agreement of redundant records which are necessarily entered in a redundant manner to meet functional requirements

DEPARTMENT OF ENERGY ENVIRONMENTAL DATA EXCHANGE NETWORK PROJECT

Robert Murray, US Department of Energy
Richard Sassoon, Science Applications International Corp

Abstract — Acquisition, use, and dissemination of environmental information are critical to meeting the mission of the DOE Office of Environmental Management (DOE-EM). Environmental information is stored in a vast array of databases, each with its own structure and definitions. This presents challenges for access, which if overcome, present a tremendous opportunity to streamline current practices.

The DOE-EM Office of Safety, Health and Security (EM-5) is developing an innovative program based on knowledge management principles to leverage new technologies to access data via the Internet from dispersed databases. Central to this process is standardization and integration of existing data. EM-5 is currently participating with other federal and international agencies in a cooperative project called the Environmental Data Exchange Network (EDEN). This project applies data mining software to simplify the acquisition and use of the data that resides in geographically dispersed database systems. The EM-5 Data, Decision, and Documentation (3D) program will present its strategy as to how it plans to leverage new and innovative web based tools to access critical data necessary to meet its mission needs.

Introduction

Effective information management is a critical component in the process needed for successful accomplishment of the mission of the Department of Energy's (DOE's) Office of Environmental Management (EM) to clean up the Nation's former nuclear weapons production facilities. Information management includes the technical and management practices necessary to ensure that the correct type, quantity and quality of data are collected, organized, analyzed and disseminated to achieve effective decision making. Good information management practices within EM will lead to: more effective management of EM technical projects; better business practices and oversight of costs; improved planning and decision-making at all levels of the organization; and the generation of more rigorous and defensible technical data to support these decisions.

Data generated and stored in a vast array of data bases and other data sources within EM is only useful to the organization if it can be converted into environmental technical information that is easily available and accessible to key decision-makers within EM. This notion is illustrated in Figure 1. Key to successful implementation of this concept is the standardization and integration of data which allows the decision-maker common access to multiple data sources and the ability to obtain critical information.

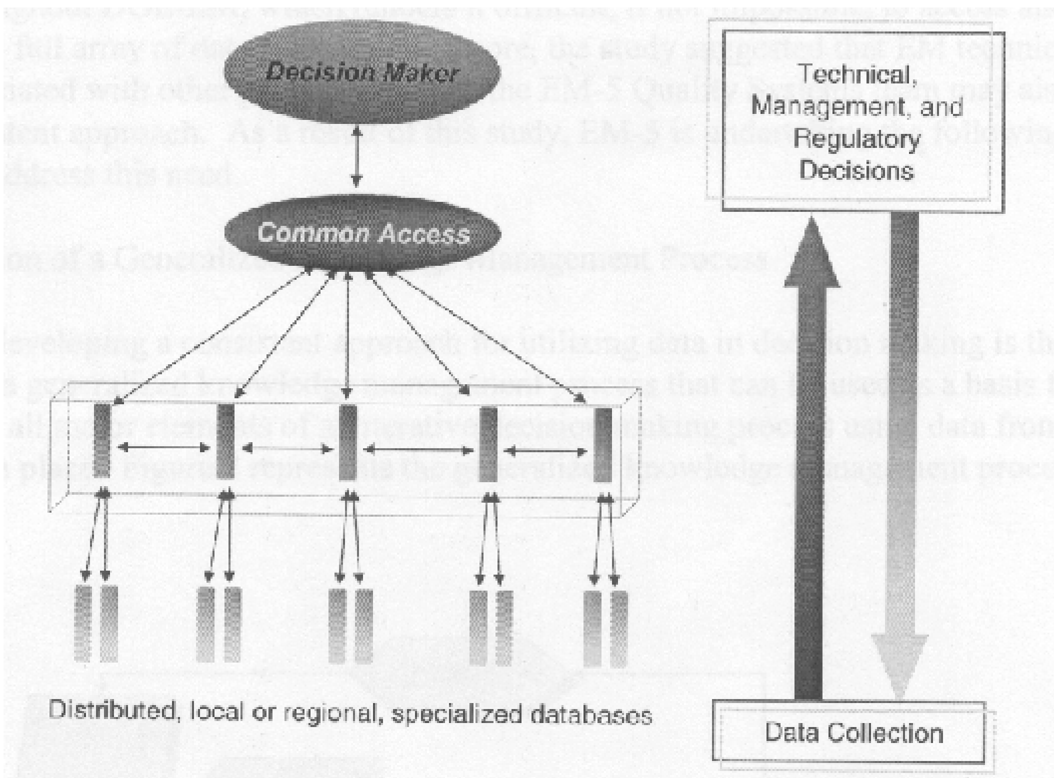

Figure 16: Effective Information Management

DOE EM-5 Role

The Office of Safety, Health and Security (EM-5) within EM is tasked with a variety of technical and management roles that are central to the execution of the DOE-EM mission. These include: EM safety and health, establishment of safety requirements for the packaging used in EM shipments; supporting EM in addressing its safeguards and security concerns; and developing and maintaining programmatic quality systems in the areas of quality assurance; analytical services, emergency management, and risk management. In order to leverage for EM the array of data produced and used by these diverse programs, a knowledge management approach is being developed within the Data, Decision and Documentation Program (3D) of the EM-5 Quality Systems team. Knowledge management is the science of using structured and unstructured data from a variety of sources to obtain information oriented toward making a specific decision. This approach requires the development of tools to integrate information within existing EM-5 databases.

EM-5 Strategy

EM-5 recently conducted a survey of managers of EM analytical information and database systems to determine whether a consistent approach for utilizing data in decision making would be of value. This study revealed that there is a general lack of integration among analytical data systems throughout DOE-EM, which renders it difficult, if not impossible, to access and utilize data from the full array of databases. Furthermore, the study suggested that EM technical data sources associated with other program areas of the EM-5 Quality Systems team may also benefit from a consistent approach. As a result of this study, EM-5 is undertaking the following activities to address this need.

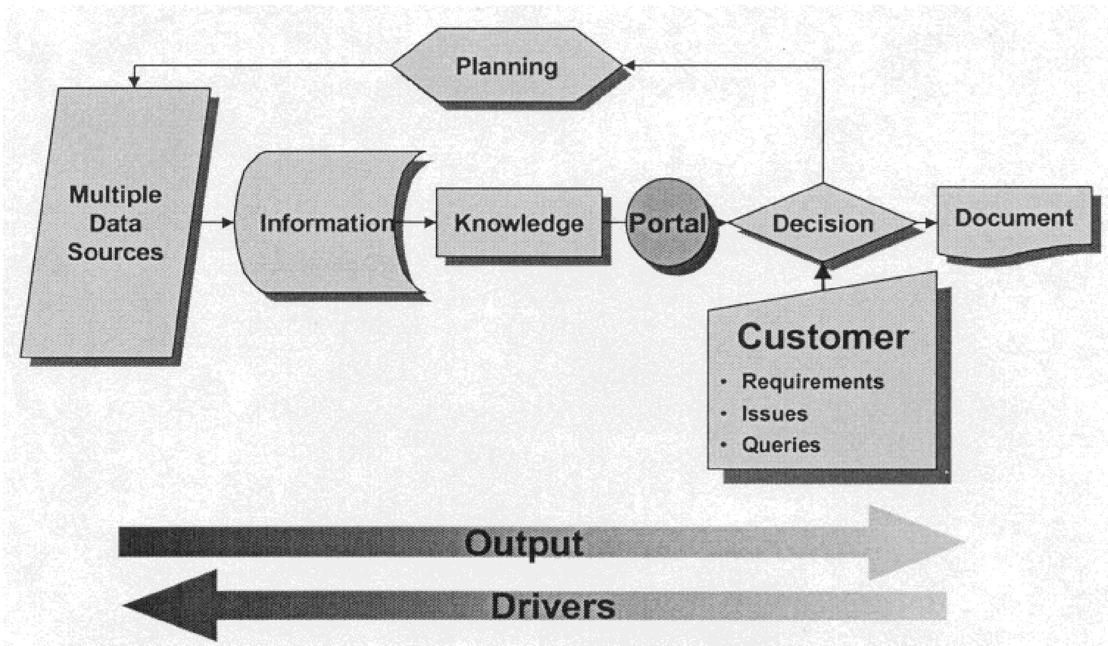

Figure 2: Generalized Knowledge Management Process

- Definition of a Generalized Knowledge Management Process

Essential to developing a consistent approach for utilizing data in decision making is the definition of a generalized knowledge management process that can be used as a basis for ensuring that all major elements of an iterative decision making process using data from multiple sources are in place. Figure 2 represents the generalized knowledge management process defined by EM-5.

Central to this process is understanding customer and regulatory drivers to define the key decision to be made and how that decision will be documented. The planning stage determines what type and quantity of data must be accessed, converted into useful information to become knowledge on which the decision is based. The portal is the mechanism through which various data sources are accessed. The process can be repeated and modified though numerous cycles until sufficient knowledge is acquired to render a defensible decision.

EM Oversight of the Environmental Data Exchange Network (EDEN) Demonstration

An example of the application of this process is the Environmental Data Exchange Network (EDEN) demonstration, which is illustrated in Figure 3.

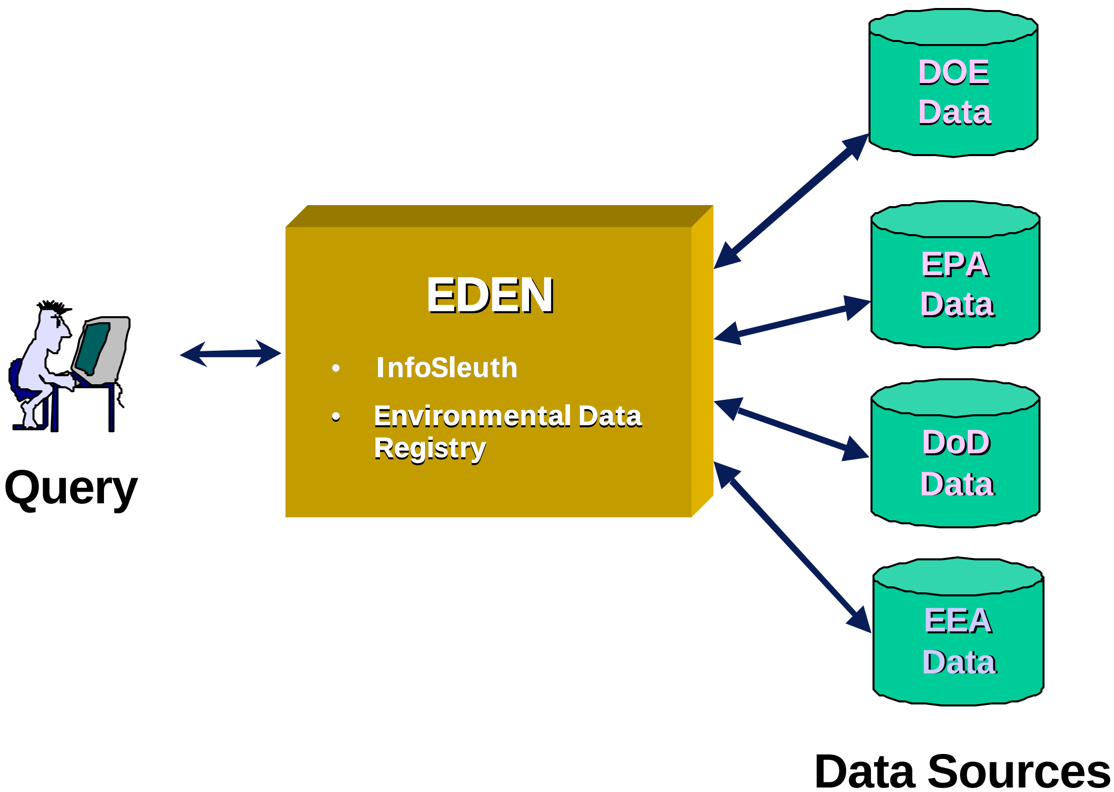

Figure 3: Environmental Data Exchange Network

DOE has teamed with the US Environmental Protection Agency (EPA), the US Department of Defense (DoD) and the European Environmental Agency (EEA) to demonstrate sharing of environmental information and data from a set of eight diverse and geographically dispersed database systems from each of the participating agencies. Each of the participating agencies has a vested interest in the acquisition, use and dissemination of environmental information. EDEN permits the exchange of information among organizations through the establishment of a common environmental vocabulary, which is now being defined in EPA's Environmental Data Register (EDR). EDEN then uses InfoSleuth® data mining software to acquire, analyze, and summarize the data that resides in the multiple database systems in response to a query made by the user.

After an initial proof of concept was demonstrated at EPA, an advanced EDEN pilot demonstration is currently being conducted on the DOE Office of Environmental Safety and Health (EH) information portal, and EM-5 has a lead role in overseeing this important activity. Once fully developed and implemented, EDEN will be accessible to any organization or individual through a standard Internet browser. Successful demonstration of the EDEN concept will yield a tool to access multiple databases without restructuring existing data.

Application of Knowledge Management Tools to EM-5

After the knowledge management process is accepted, and the EDEN concept fully demonstrated, these tools will first be applied within EM on the programs and activities within EM-5. Data will be integrated from multiple data sources associated with, for example, analytical services, emergency response, risk avoidance, waste shipment packaging, and safety and health through a consistent knowledge management process. This is expected to enhance the effectiveness of each of these programs and provide benefits across all of EM.

Conclusion

Information management is a critical component of environmental program execution. Ready access to a wide array of data increases confidence in decision making and reduces risks associated with decision errors. The ability to acquire data from geographically and technically dispersed databases presents several tangible benefits to the decision-maker. The primary benefit is that data can be extracted from existing sources, thereby eliminating the need to collect and process additional redundant data. DOE-EM recognizes the value in this approach and EM-5 is taking the lead in developing and applying these concepts.

THE OEI BEST PRACTICES SERIES FOR ANALYTICAL INFORMATION PRODUCTS

Evangeline Tsibris, U.S. EPA, Office of Environmental Information

Abstract — EPA's Office of Information Analysis and Access (OIAA) is developing a Best Practices Series for analytical information product development. Building on the findings and recommendations of the OEI report, "Lessons Learned about Designing, Developing and Disseminating Environmental Information Products," OIAA is leading the Agency wide effort to develop and release guidance documents on each important phase of the information products lifecycle: planning, design, development, review, release, maintenance and close-out. Each guide will consist of EPA examples of best practices, case study applications of these practices, and reference to pertinent policy/guidance that already exist. OIAA welcomes participation on the Best Practices Team for this important effort.

Background

EPA maintains a large and complex holding of public data. Most of the information is generated from regulatory reporting requirements, such as emissions monitoring, but the Agency also maintains public records on ambient monitoring and remote sensing; various regulatory and voluntary program activities; and compliance records. Once collected and compiled, Program Offices and Regional Offices use the information for managing their programs, for decision-making, and making portions of it available for public use. Importantly, the Agency is using this data to create *analytical information products* that summarize and interpret the information which facilitate the use and understanding of EPA's data. Creating accurate and appropriate information products often reduces the complexity of information being made public, but may also reduce the transparency of how the information has been processed and is being presented.

EPA's work to create information products and educate users is now moving at a speed that requires a more consistent and thorough approach to the planning and development of analytical information products. One of the first steps toward understanding what makes a product widely used, relevant and technically credible has been background research conducted under an advisory committee comprised of representatives of all AAships and the Regions. The final report, *Lessons Learned about Designing, Developing and Disseminating Environmental Information Products*, documents the diverse types of products and corresponding steps of product development, and the current issues that interviewees emphasized for attention in order for environmental information products throughout the Agency to be of the highest quality.[1] Importantly, the findings are distilled from interviews with information product developers themselves.

Critical areas for improvement identified by product developers included:

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[1] EPA 260R-00-001

- Articulate a clear sense of the product's purpose early in the design process. As obvious as this may seem, interviewees stress that this step is frequently overlooked, resulting in redundancy among products, sub-optimal user functionality, and other problems.

- Avoid attempts to develop a generic information product. While information products do circulate beyond their intended audience, this should not be used as a rationale for avoiding the need to specify a target audience and its unique needs for environmental information.

- Develop a mechanism to facilitate communication among producers and users of EPA data. While some users of secondary information products take the initiative and communicate effectively with originators of data, EPA currently lacks an organized framework to guide this kind of technical interaction.

- Seek stakeholder and product audience input at all points in the information product life-cycle. Early stakeholder involvement is especially important to help clarify goals, reduce skepticism, build consensus, and ensure the dissemination of information that meets audience needs.

- Address concerns over data accuracy. Some developers and managers interviewed note the importance of creating a *data feedback loop*, through which facilities and other data providers are asked to verify data used in a particular information product. Beyond data verification, some interviewees also feel that the Agency should consider initiating an internal comment period via an intranet-accessible form, allowing data to undergo internal scrutiny prior to public release.

Information product developers probably recognize these issues as those they wrestle with day-to-day. However, such challenges are perhaps less obvious but not of lesser concern, to internal and external users of environmental information.

What is the Best Practices Series?

The challenge facing the Agency at this time is the need to grow and enhance the infrastructure that supports the way analytical information products are developed so that:

- EPA product developers are given the guidance they need to create credible information products with sound data; and

- all information product <u>users</u> receive the information they want and the guidance they need to understand the information received.[2]

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[2] EPA Strategic Plan Goal 7: *Expansion of American=s Right to Know about Their Environment*
Objective 7.1: Increase the availability of quality health and environmental information.

To these ends, an Agency-wide network of staff involved with information product development is being convened to research and eventually develop a series of Best Practices Guides for information product developers and managers. The series of guides will span the product life cycle from initial conceptualization through development, testing, and maintenance, and will provide practical advice and examples of excellence. And while OIAA will be coordinating these efforts, the participation of a wide range of staff throughout the Agency is the most critical input to creating a successful Best Practices Series.

Purpose

There are existing Best Practices around the Agency that should be highlighted in order to promote Agency information sharing, thereby strengthening information partnerships and strengthening the EPA information infrastructure. OIAA has adopted a best practices approach for several reasons:

- It is among the simplest means of demonstrating tried and true success and helping other implement that success in their everyday business.
- It is a voluntary, rather than command and control approach. Tools to help information product developers will be created, instead of rules. This approach emphasizes and illustrates attention to excellence throughout the product development process by fostering partnerships and collaborations.
- Because it is a process involving many offices and individuals, there are opportunities for such partnerships, as with the Office of Research and Development Environmental Information Management System (EIMS), the OEI Information Products Bulletin (IPB), the Office of Communication, Education and Media Relations (OCEMR), the data quality efforts of OEI's Data Quality Staff and other quality efforts around the Agency, thereby connecting the information product experts around the Agency under one guidance objective.
- In addition, this series will complement other ongoing government-wide best practices efforts.

The Best Practices Series, the Best Practices Network, and the very process of developing the series will also generate direct benefits for product developers, the Offices sponsoring the development of information products, and users. On the development side, the Best Practices Series will streamline product development, thereby reducing costs and duplication of effort. On the user side, better coordinated development and products of higher quality will be more credible and increase the likelihood that those seeking environmental information from EPA will get the answers to their questions more quickly and in a form that is more understandable. As the best practices approach is applied to analytical information product development, the Agency will provide all users with the true power of its environmental information holdings.

Objective 7.2: Improve the public=s ability to use and understand environmental and health information.

Development Plan

Successful development of the Best Practices Series is very much dependent on OEI=s ability to organize and support an effective Agency work process. The planning, research and review process is a collaborative effort of staff throughout the Agency and will take place throughout the life of the project. A network of staff in program and Regional offices will contribute their collective expertise and experience to the initial research and review phases. The work of researching and developing draft Guides is the responsibility of a smaller Best Practices Team, coordinated by OEI. The involvement of the Best Practices Network and the Best Practices Team will ensure that the Best Practices Series creates the most relevant and useful guides possible. It is important to note that the Best Practices Network consists of Agency volunteers and these key contacts are critical to the success of the series as a whole. Please note that the potential for external (non-EPA) stakeholder participation is one that is still being considered by OIAA in the context of how best to deliver a valuable product to our audience, the EPA product developer. The ultimate deliverables are an interactive website consisting of a Best Practices toolkit, feedback forum and library, to assist users with implementing best practices into their everyday project and communicating with others in this information community. In addition to the website, the Series will produce 12 hardcopy guides that will be maintained as living documents into the future. Four topics have been selected for priority development: *Metadata Development*, *Product Review*, *Environmental Indicators,* and *Conducting a Data Suitability/Quality Assessment*.

Structure of the Best Practices Guides

Each of the Best Practices Guides will have a similar structure and will include:

- *Examples of EPA Best Practices* B The initial step of guidance development is the identification of existing practices as candidates for inclusion into a Best Practices guide. Agreed-upon best practice criteria will then be applied to determine which findings can be showcased as examples of *best* practices. These examples will then potentially be used in at least one case study application, and pending further revision, will ultimately be recommended for Agency use.

- *Best Practices Case Studies* B each guide will contain examples of best practices along with at least one case study that demonstrates the application of some or all of these practices. By providing these examples and case studies the guides will enable information product developers and managers to adapt the guidance to their specific needs and situations. For example, the guidance on effective stakeholder involvement might include a more in depth look at how one Office engaged external groups in the development and final release of their product, including a detailed history of how the project accomplished its objectives, the role of each stakeholder groups, and the resources involved.

- *Resources* B each guidance recommendation will also be contextualized within the necessary framework of existing guidance and policy, both within the Agency and outside the Agency.

- *OEI Recommendations* B each guide will include recommendations that delineate the best practice or best practices for that topic area, and how to implement that practice. These recommendations will be based upon the research conducted by the Team that resulting in the examples of best practices, the findings from the multiple case study applications and the relationship between the teams findings and existing policy and/or guidance. Each recommendation will be expressed in the form of practical advice product developers and product managers.

Network Building

A network of interested and involved stakeholders is critical to the development, dissemination and use of the guides. These stakeholders include: current, past, and future product developers; current information users; primary data system stewards; and the management staff in all Agency Offices and Regions. These stakeholders will be actively solicited for their expertise, opinions, and assistance in reviewing proposals and draft material for the Series as it is being developed. As a first step, OEI is asking all interested individuals to sign up for future bulletins (email tsibris.evangeline@epa.gov) and is developing a method to keep the network informed of current and planned activities.

The Best Practices Team

The Best Practices Team will oversee development of the Best Practices Series. Currently, the Team consists of representatives from OEI, the Office of Communications, Education and Media Relations (OCEMR), EPA Region 5, and EPA Region 3. The Team will be instrumental in guiding the research on best practices within each topic area, as well as the development of series and interactions with the Network and Agency management. OEI will be soliciting nominations for a lead staff person from each Office and Region to serve on the Team.

Research

The initial stage in the development of the Best Practices Series has been the needs assessment and definition of scope for the entire effort. For each Series topic, previous related research will be collected and summarized to identify best practices, and to develop guidance criteria. Additional research on each topic may be undertaken following review of the draft Guide.

Best Practice Criteria & Evaluation

A critical part of developing the Best Practices Series is to determine what constitutes best practices and how to evaluate their appropriateness to Agency information products.
In this step, the initial criteria are evaluated for their utility and appropriateness using with existing information products. Testing the draft criteria helps to determine 1) if there are gaps in issues addressed by the draft criteria; 2) if additional text explanations are required to help developers understand or use the criteria; and 3) to identify real-world examples to bring into the Guide.

Finally, once the initial testing of the criteria is complete, the criteria will be incorporated into the draft Guide and distributed to interested stakeholders in order to obtain feedback from the widest possible group of reviewers. This review procedure will also help determine if further research is needed before proceeding to finalizing the particular guidance document.

Publishing of the Series

OEI intends to publish the twelve Best Practices Guides individually as the research, evaluation, and review are completed for each topic (it is not expected that they will be completed in order). They will be published simultaneously in both hard copy and via the Best Practices Intranet website. This website will contain downloadable pdf guides in addition to a more-indepth look at each topic area and links to other related materials on key subject matter. This website will enable interested parties to submit comments, questions, or even their own recommendation for a best practice while also searching for information resources they need.

Maintenance of the Series

The Best Practices Team and OEI will be responsible for maintaining the Series. It is expected that each Guide will be updated and/or completely redone periodically as practices, information, and technologies evolve. Consequently, the web-based version will be actively maintained and updated as living tools for information product developers. This approach also allows interested parties, even if not involved in the original development of a Guide, to provide comments on an ongoing basis, which can be incorporated into any subsequent revisions of the Guides.

External Stakeholders

Much of EPA's data is collected for regulatory purposes, when this data is used in analytical information products there are many external stakeholders who have a legitimate interests in these activities. External stakeholders such as state agencies, industry associations and environmental groups will have strong opinions on what EPA's best practices should be for analytical information products. Options for establishing the proper forum to receive stakeholder comments will be initiated.

Topic Areas for the Best Practices Series

Each stage of product development will be supported by one or more guidance documents. The following is a list of these product development stages and the Best Practices Guides currently proposed for each stage:

<u>Product</u> <u>Planning</u> <u>Stage</u>:

1. Product Plan B identifies best practices and offers advice on creating a strategic plan for product development and for the project as a whole, including factors such as budgetary constraints.
2. Audience Identification B identifies best practices and offers advice on identifying audience(s) for the product.

3. Stakeholder Involvement B identifies best practices and offers advice on determining when and how stakeholders should be involved in the product development.

Product Design Stage:

4. Product Design B identifies best practices and offers advice on designing the best product based on its information content, function, audience, project goals and performance measures.
5. Data Suitability Objectives B identifies best practices for assessing how well existing data meets the objectives and purposes of an analytical information products.

Product Development Stage:

6. Metadata Development B identifies best practices and offers advice on preparing supporting explanations and caveats that facilitate appropriate data/product use and understanding.
7. Using Environmental and other Indicators B identifies best practices and offers advice on the development and appropriate use of environmental indicators.

Product Publishing Stage:

8. Product Review and Release B identifies best practices and offers advice on fulfilling all requirements for product review and release.

Maintenance & Revision Stage:

9. Product Maintenance and Close-out B identifies best practices and offers advice on planning for and carrying out product maintenance for the anticipated life of product.
10. User Feedback and Revision B identifies best practices and offers advice on creating and implementing a user feedback and revision process.
11. Error Correction B identifies best practices and offers advice on implementing an error correction process once the product is released and users are able to provide feedback.

Process/Next Steps

Four Best Practices Guides are currently in the initial stages of development. Once each guide is completed, it will be published in both hard copy and on the Best Practices Intranet site, where it can be periodically revised and updated. The best practices team will be developing an Agency-wide network to assist in identifying best practices examples and to review draft documents and website material.

OVERVIEW OF EXECUTIVE ORDER 13148: REQUIREMENTS FOR ENVIRONMENTAL MANAGEMENT SYSTEMS AT FEDERAL FACILITIES

Gary L. Johnson, U.S. EPA, Office of Environmental Information

Abstract - In April 2000, the White House issued Executive Order 13148, Greening the Government Through Leadership in Environmental Management. This Order applies to all appropriate Federal facilities that have operations which interact with the environment and includes a number of environmentally-related requirements. The most significant requirement is that all appropriate Federal facilities must implement an Environmental Management System (EMS) by December 31, 2005. This Order affects Federal laboratories, testing facilities, maintenance facilities, hospitals, etc., across all Federal departments and agencies.

INTRODUCTION

The genesis of the Executive Order 13148, *Greening the Government Through Leadership in Environmental Management,* stems largely from the expectation of Federal leadership in environmental management; that is, there should be a reasonable expectation that the Federal government would set a leadership position for business and industry to follow in implementing effective environmental management. Moreover, environmental management must be a fundamental and integral component of the Federal government's operations, and must apply to all applicable facilities.

While the EMS requirements in the Order cite the Code of Environmental Management Principles (CEMP), the *de facto* requirements are based on ISO 14001:1996, *Environmental Management Systems - Specifications with Guidance for Use*. Because EMS defined under ISO 14001 may be very similar to quality management systems (QMS) defined under ISO 9001:2000 or ANSI/ASQC E4:1994, it is possible that quality assurance professionals may be asked to assist their organizations in developing and implementing an EMS.

The goals of the Executive Order are broader than environmental management and encompass several important environmental activities. These goals are:

- Environmental management, including the establishment of environmental management systems;
- Environmental compliance, including the establishment of audit programs to ensure that statutes and regulations are met;
- Right-to-know and pollution prevention, to keep the public informed about te environmental aspects of Federal facilities and to focus efforts on preventing releases of pollution from them;
- Release reduction of toxic chemicals, through more effective facility management and innovative technology use, by 40% by the end of 2006;
- Reduced use of toxic chemicals and hazardous and other substances, through use of

substitutes, pollution prevention, and improved facility management, by 50% by the end of 2006;

- Reductions in ozone-depleting substances, through the use of alternative materials, to phase out the procurement of Class I ozone-depleting substances by the end of 2010; and
- Implementation of environmentally and economically beneficial landscaping practices at all Federal facilities.

PLANNING AND ACCOUNTABILITY

The responsibility for implementing the Executive Order is assigned to each agency and department head. Agencies and departments are instructed to place high priority on obtaining funding for implementation of this Order and other "Greening" Executive Orders. To enable more effective tracking of environmental effectiveness, the Executive Order requires that Federal agencies and departments implement Life Cycle Assessment (LCA) methodologies and environmental cost accounting principles in their operations.

By April 2001, each agency and department shall have policies, strategies, and plans in place to:

- Incorporate all requirements of the Executive Order,
- Develop an environmental management strategy for the organization,
- Develop pollution prevention plans, and
- Submit an annual progress report to the Administrator of the Environmental Protection Agency.

To facilitate the implementation of the Executive Order, the EPA was directed to convene and chair an Interagency Environmental Leadership Work Group, composed of senior-level representatives from all agencies and departments, which would monitor the progress of the Federal government's progress and provide a forum for discussing emerging issues and questions.

IMPLEMENT AGENCY AND FACILITY ENVIRONMENTAL MANAGEMENT SYSTEMS

The cornerstone of the implementation of the Executive Order is the establishment of Environmental Management Systems (EMS) at all appropriate facilities. An EMS is:

> "the part of an overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, procedures, processes, and resources for developing implementing, achieving, reviewing, and maintaining an organization's environmental policy."

The Executive Order defines a process for implementing an EMS at applicable Federal facilities. It is important to understand that because of differing processes used and varying environmental conditions from facility to facility, each EMS is unique to a particular location and facility. Therefore, for each applicable facility, Federal organizations are directed to:

- Conduct EMS self-assessments by October 2001 based on the Code of Environmental Management Principles (CEMP) (Ref.1),
- Implement pilot EMS projects (as needed) by April 2002, and
- Complete EMS implementation at all facilities by December 31, 2005.

Coupled with the EMS implementation are the requirements for facility compliance audits and EMS training for managers and staff. The facility compliance audits provide a systematic means of assessing regulatory compliance at facilities and must be performed at least every three years. Consideration should be given to the size and complexity of the facility when planning for such audits. Training for managers and staff is essential if the EMS implementation is proceed effectively. Moreover, inasmuch as the EMS concepts and practices may be new to many Federal managers and staff, training in the use of the EMS is critical to achieving the organization's environmental goals.

EPA ROLE

The U.S. EPA has several roles in the implementation of this Executive Order, including:

- Providing general oversight for government-wide implementation,
- Providing technical assistance on EMS implementation and audits,
- Establishing an Environmental Leadership Awards program by April 2001 to promote and recognize performance among Federal organizations,
- Providing technical advice and assistance to Federal organizations on compliance with the Executive order and with applicable environmental regulations, including the establishment of a Compliance Assistance Center by April 2001, and
- Providing compliance assurance in general.

The compliance assurance responsibility includes:

- Conducting reviews and inspections for determine compliance with regulations,
- Reviewing corrective action plans from non-complying agencies and departments, and
- Providing an annual report on compliance to the President.

ENVIRONMENTAL MANAGEMENT SYSTEMS

As noted previously, the EMS is the critical part of the Executive Order. Moreover, the Executive Order cites the CEMP, which was developed by EPA as enforcement compliance tool, as the official basis for an EMS. As a practical matter, however, the *de facto* basis for the EMS is ISO 14001:1996, *Environmental Management Systems - Specification with Guidance for Use* (Ref. 2).

ISO 14001:1996 is an international consensus standard which has also been adopted as an American National Standard. ISO 14001 clauses provide specifications for:

- General requirements,
- Environmental policy,

- Planning,
- Implementation and operation,
- Checking and corrective action, and
- Management review.

As noted earlier, an ISO 14001 EMS provides for the management of an organization's environmental aspects and impacts; that is, how the organization interacts with the environment and what impact (either positive or negative) that results from such interactions. Management is responsible for setting environmental goals and objectives for the organization to achieve. There are two tools available to help management examine the effectiveness of the EMS:

- ISO 19011, *Guidelines on Quality and/or Environmental Management Systems Auditing* (Ref. 3), and
- ISO 14031, *Environmental Performance Evaluation (EPE) - Guidelines* (Ref. 4).

Audits provide for determining conformance to ISO 14001 and the effectiveness of the EMS implementation. EPE is used by management to evaluate the performance of the EMS against the defined goals and objectives for the organization.

As an auditable specification standard, organizations may choose to seek third-party certification to ISO 14001. Several Federal facilities have achieved ISO 14001 certification, and more are expected to do so. The Executive Order applies to all Federal facilities that interact with the environment; therefore, it is logical to assume that many facilities will be affected. The number of facilities needing an EMS will vary widely by agency and department.

GENERAL STEPS FOR EMS IMPLEMENTATION

The following general steps may be used to implement an ISO 14001-based EMS at an applicable Federal facility:

- **Get management buy-in at facilities** - This is a key step. With full management understanding and support, implementation of an effective EMS will be difficult, if not impossible.
- **Define an EMS policy for the organization** - The policy should reflect the mission of the organization and its likely environmental aspects and impacts. More importantly, the policy should be realistic and achievable.
- **Survey facilities for environmental aspects and impacts** - As noted previously, each facility is unique in terms of its immediate environment and the effect its operations have on the environment. This survey is key to understanding the scope and extent of the aspects and impacts.
- **Develop a work plan for EMS implementation** - A work plan provides a road map for what must be done to implement the facility-specific EMS.
- **Develop a cost estimate for implementation** - The cost of implementation will vary. Consideration should be given to the use of consultants to assist the organization in

planning for the EMS and training of managers and staff. The organization should also decide if it wishes to seek certification to ISO 14001 and factor into the estimate those costs.

- **Conduct self-assessments at facilities** - Such assessments will help to identify the full range of aspects and impacts from the facility's operations. It may be appropriate to conduct a "gap analysis" to define missing elements. Again, the use of consultants may be helpful if the facility staff lacks the needed knowledge and experience in EMS implementation.
- **Implement a pilot EMS (if appropriate)** - If a facility is very complex, it may be useful to conduct a pilot EMS on a portion of the operations in order to better understand the processes involved and to obtain practical experience for managers and staff. For example, a pilot EMS may focus on a facility's analytical laboratory operations.
- **Train staff** - Training is essential if the EMS implementation is to be effective. The training should be based on the integration of the EMS concepts and practices with the operations performed at the facility.
- **Develop and initiate an audit program** - An audit program will provide important information on the EMS implementation. First, it will show if the required EMS elements have been addressed by the facility and, second, it will indicate over the long term if the elements have been implemented as prescribed.
- **Conduct gap analyses at facilities** - The gap analyses will enable the organization to identify anything missing from the EMS design. This information will enable the organization to make any corrections in the EMS design.
- **Develop and test the EMS at each facility** - Testing the design will identify any remaining flaws from EMS planning and possibly uncover potential problems not considered during planning. Testing will provide the ultimate measure for the proposed EMS before the final commitment to implementation.
- **Train EMS Coordinators for each facility** - The success of the EMS implementation and the achievement of the organization's goals and objectives may rest partially on the ongoing ability of the facility to adjust to needed changes in the EMS. An EMS Coordinator provides "resident expertise" on the EMS and is a valuable resource to assist managers and staff in resolving EMS-related issues. Since it is unlikely that such expertise existed previously at a facility, the EMS Coordinators must be trained in order to equip them to perform this function.
- **Implement the final EMS** - When the testing has been done and staff have been trained, the facility should implement its unique EMS design. The implement-ation must be full and complete in order to be effective.
- **Audit the EMS for conformance to the standard** - Audits should be performed on a routine basis by appropriate auditors. Audits may be performed by facility staff trained as auditors (i.e., internal auditors) and by auditors from an independent, outside organization (i.e., external auditors).
- **Evaluate the EMS effectiveness using EPE** - Use of the EPS process will measure the effectiveness of the EMS in meeting the goals and objectives on the organization for its EMS. Moreover, EPE can identify improvements to the EMS that management may wish to consider.

CHALLENGES AHEAD

Federal agencies and departments are responding to Executive Order 13148, but progress has been slow. Several key challenges remain, including:

- Getting managers and staff educated about EMS concepts and principles,
- Understanding the scope of the Executive Order, and
- Meeting the interim and final deadlines and goals.

EMS concepts and principles are largely "foreign" to most Federal managers (at any level) and to staff in general. Their education on EMS, particularly in terms of the value that EMS can bring to an organization, may be the largest challenge. Attaining a working understanding of EMS concepts and practices becomes central to understanding what an EMS means. This will take time and training.

As note previously, numerous interim deadlines have been specified in the Executive Order, including deadlines for environmental policy and EMS pilots. To date, measurable progress has been difficult to document; however, the final completion date of December 31, 2005, is less than five years away. As time passes, that deadline looms as the major challenge posed by the Executive Order. It remains to be seen if that goal will be met.

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